BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL
(WESTERN ZONE BENCH), PUNE
AT PUNE

O.A. NO. 56/2018

Nikhil Vidhyadhar Joglekar & Ors. ...Applicants

Versus

Ministry of Environment, Forests
and Climate Change &Ors. ...Respondents

AFFIDAVIT IN REPLY BY RESPONDENT NO.13 (TTK HEALTHCARE LIMITED)

I, Brijj Balaji Singh, Age: 54 years, Occupation: Senior Vice President, at 30, Wood Creek County, Phase 1, Nandambakkam, Chennai 600016, a Authorized Signatory of TTK Healthcare Limited, a company registered under the provisions of the Companies Act, 1956 having its registered office at No. 6, Cathedral Road, Gopalapuram, Chennai – 600086, Tamil Nadu, the Respondent No. 13 herein, do hereby solemnly state on oath and affirm as under:

1. I say that at the outset, the averments made in the present Original Application No. 56/2018 ("**said Application**") are false, baseless, erroneous, misconceived, without any merit, vague, misleading and not maintainable, hence unless

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specifically admitted herein, the same may kindly be treated to have been denied. Nothing stated in the said Application shall be deemed to be admitted due to lack of specific denial or traverse. The said Application deserves to be dismissed *in limine*.

2. The Respondent No. 13 has filed on record before this Hon'ble Tribunal its Preliminary Objections dated 28.08.2018, the contents of which are reiterated but not repeated herein for the sake of brevity and the same may kindly be treated as a part and parcel of this Affidavit-in-Reply.

3. The Respondent No. 13 is a part of the TTK Group (one among the top 5 condom manufacturers in India) which was started in the year 1928 by Late Shri. T. T. Krishnamachari, and has a remarkable and invigorating trend toward using branding in marketing concepts and techniques, while the condom manufacturer started as an indenting agency (an agent of a company located in another country) for household brands. By 1940, the condom manufacturer had accomplished more than a decade of tremendous growth and started offering a new breed of products. The said business group hadjoint ventures with global corporations such as SSL International (the condom manufacturers of Durex condoms). It would only be apt to say that the TTK Group

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had spearheaded the "Nirodh" revolution in India – from establishing India's first manufacturing plant in 1963 to installing the country's first electronic testing facility to introducing India's first non-subsidised "Nirodh" in 1974. The said period was not precisely the time when society thought much about contraception or populace; it is at that the time when Respondent No. 13 had entered the Indian "Nirodh" market. The Respondent No. 13, a trailblazer of condom production and marketing in the whole of India, has pioneered various developments, which had resulted in a giant leap in the condom technology, in the industry.The Respondent No. 13 was the first to build a manufacturing plant and to build an electronic testing facility just to produce the best condoms in India. The Respondent No. 13 was the first to launch the country's 1st non-subsidised condom in 1974 and to introduce variants in condoms and pleasure increasing accessories.Now, Respondent No. 13 has grown itself to a capacity of producing around 150crore condoms per year. The Respondent No. 13have beenexporting over 100 crore condoms every year to almost all the European and American countries. And thus, it would only be apt to say that Respondent No. 13 is one of the largest manufacturers of condoms in the whole world.In the process of becoming one of the largest condom manufacturers of the world, Respondent No. 13 also managed to win many prestigious awards. A few of which,

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worth mentioning are (i) JIPM's Award for TPM Excellence, (ii) CII's Award for the Excellent Water Eficient Unit, (iii) National Award for Leadership Excellence in Safety Health and Environment, (iv) Best Exporters Award from CAPEXIL, etc. It is humbly submitted that Respondent No. 13 has always adhered to the international as well as Indian standards and complied with the applicable laws, rules and regulations with respect to manufacture, packaging, sale and distribution of condoms.

The copies of licenses, permissions and certificates obtained by Respondent No. 13 from the concerned Indian authorities and from international organizations are collectively marked as "**Annexure 1 (colly.)**" and annexed hereto.

4. The Respondent No. 13 manufactures and distributes the product "natural rubber latex condom" under its brand name "SKORE" in the Indian market. The products manufactured by Respondent No. 13 primarily consistof natural rubber latex (more than 97%) and a few chemicals/ lubricants (which are less than 3% of the total product). It is submitted that the said products can be consideredas bio-degradable. The products of Respondent No. 13 are manufactured in line with International Standard ISO 4074:2015.

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5. The Respondent No. 13, being one of the largest manufacturer and distributor of condoms, has been instrumental in controlling unwanted pregnancies, ensuring health and safety of people, preventing of sexually transmitted diseases such as HIV & AIDS, controlling population growth, etc.

6. The Respondent No. 13 has undertaken several social and environment related activities/ programmes as a part of its as a part of its 'Corporate Social Responsibility' and 'Corporate Environment Responsibility', some of which are listed below:

   (i) Running of voluntary blood banks at Chennai and Bangalore with latest equipment;
   (ii) Running of de-addiction centre in Chennai for alcoholics and drug addicts;
   (iii) Conducting of AIDS awareness programmes regularly;
   (iv) Actively associated with Indian Cancer Society;
   (v) Supporting of TT Narsimhan Swami Dayananda Higher Secondary School, Manjakkudi, Tiruvarur, where around 1,500 children are studying;
   (vi) Plantation of around 3 lakh saplings across Tamil Nadu.

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It is humbly submitted that even during the Covid-19 pandemic, the Respondent No. 13 provided Covid shield standing racks in Thirubhuvanai, chairs and sanitizers in Ariyur and an ambulance facility in Puducherry.

Copies of the relevant documents pertaining to the social and environment related activities/ programmes of Respondent No. 13 are collectively marked as "**Annexure 2 (colly.)**" and annexed hereto.

7. It is humbly submitted that in spite of promoting use of condoms, complying with the applicable laws, rules and regulations, adhering to international standards and norms and working for public welfare, the Respondent No. 13 has been unnecessarily dragged into the present proceedings by the Applicants with ulterior motives and *mala fide* intentions. It is reiterated that the present proceedings are false, baseless, erroneous, misconceived, without any merit, vague, misleading and not maintainable. The said Application deserves to be dismissed at the threshold.

PARA-WISE TRAVERSAL:

8. The contents of Paragraph Nos. 1, 2 and 3 of the said Application are not known to Respondent No. 13 and do not

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merit any response. The Applicants be put to strict proof of the same.

9. The contents of Paragraph No. 4 of the said Application show that the Applicants have not made any written representation to the Respondents on the alleged issues/ grievances raised in the case at hand. The Applicants have unnecessarily rushed to this Hon'ble Tribunal under the pretext of filing an "environmental interest litigation (EIL)" on the basis of misconceived and imaginary grievances. The said Application is prematurelyfiled, not maintainable and liable to be dismissed.

10. The contents of Paragraph No. 5 to 12 of the said Applicationdo not concern this Respondent No. 13 but they appear to be generally true and correct.

11. The contents of Paragraph No. 13 of the said Application are misconstrued, vague and denied. It is humbly submitted that the provisions of the Solid Waste Management Rules, 2016 ("**SWM Rules, 2016**") are applicable only to manufacturers or brand owners of disposable products and sanitary napkins and diapers and not applicable in any manner to manufacturers or brand owners of condoms. Assuming and not admitting that the SWM Rules, 2016 were applicable to manufacturers or brand owners of

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condoms, there is no mandatory requirement under the SWM Rules, 2016 for the manufacturers of condoms to provide a pouch or wrapper for disposal of each condom with each packet of the condom.It is humbly submitted that Respondent No. 13, for some of its premium variants of condoms (which are sold at a higher price), does provide disposal pouches along with the condom. However, such a disposal pouch is not being provided with all variants of condoms due to cost constraints. In the event this Hon'ble Tribunal holds that the condom manufacturers must provide its customers with disposal pouches, it would lead to increase in the cost of the product, which will be passed on to the end user/ consumer, thereby affecting the public at large.

12. The contents of Paragraph No. 14 of the said Application do not concern this Respondent No. 13 but they appear to be generally true and correct.

13. The contents of Paragraph No. 15of the said Application are vague and not true. Assuming and not admitting that there is social and environmental injustice, as alleged, it is the duty of Respondent Nos. 1 to 8, being instrumentalities of 'State' under Article 12 of the Constitution, to remedy the said issue as per the Directive Principles of State Policy

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enshrined in Part-IV of the Constitution as well as the SWM Rules, 2016.

14. The contents of Paragraph No. 16 of the said Application are generally true and correct and do not merit any response.

15. The contents of Paragraph No. 17 of the said Application do not merit any response.

16. The contents of Paragraph No. 18 of the said Application are vague, imaginary and not completely true. As stated above, the products manufactured by Respondent No. 13 primarily consistof natural rubber latex (more than 97%) and a few chemicals/ lubricants (which are less than 3% of the total product). It is submitted that the said products can be consideredas bio-degradable. The products of Respondent No. 13 are manufactured in line with International Standard ISO 4074:2015. The averments of the Applicants that merely because condoms are not composed of 100% latex makes them non-biodegradable and that the lubricant and/or spermicidal coated and/or added to condoms may later their decomposition potential, are vague, basless, unsubstantiated and nothing but a figment of imagination of the Applicants.

17. The contents of Paragraph No. 19 of the said Application do not concern this Respondent No. 13.

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18. The contents of Paragraph No. 20 of the said Application are vague and not completely true. It is most humbly submitted that the waste generators at large are responsible for unsegregated garbage. Further, as per the SWM Rules, 2016, it is the duty of Respondent Nos. 1 to 8 to provide waste pickers with protective gear, gloves, etc. and provide them with adequate training to handle waste. The Respondent authorities must take adequate steps to curb the alleged social and environmental injustice.

19. The contents of Paragraph No. 21 of the said Application are vague and not completely true. The Respondent No. 13 provides instructions (on packets of condoms) for safe disposal of used condoms, wherein it is specifically mentioned that the used condoms should not be thrown/ flushed down the toilet.

    A copy of the cover/ packet of condoms manufactured and sold by Respondent No. 13 is marked as "**Annexure 3**" and annexed hereto.

20. The contents of Paragraph No. 22 of the said Application require no response as they do not concern this Respondent No. 13.

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21. The contents of Paragraph No. 23 of the said Application are totally false, baseless, without merit and vehemently denied. It is humbly submitted that condoms cannot, under any circumstances, be comparable with bio-medical waste under the Bio-Medical Waste (Management and Handling) Rules, 1998.

22. The contents of Paragraph No. 24 of the said Application are unsubstantiated and denied. The photographs produced on record have no evidentiary value whatsoever. The same may not be considered by this Hon'ble Authority.

23. The contents of Paragraph No. 25 of the said Application are false, misconstrued and denied. It is humbly submitted that the provisions of the SWM Rules, 2016 do not apply to this Respondent No. 13 and therefore the question of Respondent No. 13 violating the provisions thereof does not arise. The Applicants have misconstrued the provisions of law and in fact, in Paragraph No. 25(C) and (D), have misquoted the provisions of Rules 4 (1) (b) and 4 (2) of the SWM Rules, 2016. Further, Rule 4 of the SWM Rules, 2016 are applicable only to "waste generators", as defined in Rule 3 (56) thereof, and not to manufacturers/ brand owners. The Applicants, in Paragraph No. 25(E), have further misquoted and misconstrued the provisions of Rule 17 of the SWM Rules, 2016. It is respectfully submitted that the said Rule

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17 is not at all applicable to this Respondent No. 13. The Applicants are misleading this Hon'ble Tribunal and on this ground alone, the said Application deserves to be dismissed.

24. The contents of Paragraph No. 26 of the said Applicationappear to be generally true and correct. It is the collective responsibility of the Respondent authorities to implement the SWM Rules, 2016.

25. The contents of Paragraph No. 27 of the said Application are totally false, misconstrued and denied. It is the collective responsibility of the Respondent authorities to implement the SWM Rules, 2016 and not that of manufacturers or brand owners of condoms, as alleged. The Applicants are misleading this Hon'ble Tribunal and on this ground alone, the said Application deserves to be dismissed.

26. The contents of Paragraph No. 28 of the said Application are misconstrued and denied. It is humbly reiterated that in the eyes of law, it is not a mandatory requirement for the manufacturers of condoms to provide pouches along with the said products. The waste generators must dispose off used condoms in a closed dustbin or in any suitable wrapping material as instructed by the local authorities. The Respondent authorities have not ensured the same and have failed to fully implement the SWM Rules, 2016.

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27. The contents of Paragraph No. 29 of the said Application appear to be generally true and correct. The Respondent authorities have not ensured proper waste management system for disposal of used condoms and have failed in carrying out their responsibilities.

28. The contents of Paragraph No. 30 of the said Application are false, vague, misleading and denied. As far as Respondent No. 13 is concerned, there is no plastic used for manufacture of its condoms. The question of their products being non-biodegradable and being in the environment for hundreds of years does not arise and the same is nothing but a figment of imagination of the Applicants.

29. The contents of Paragraph No. 31 of the said Application appear to be generally true and correct. The Respondent authorities have not ensured proper implementation of the SWM Rules, 2016, and have failed in carrying out their responsibilities. The said Respondent authorities should provide gloves, masks, collection equipment and sufficient training to waste pickers.

30. The contents of Paragraph No. 32 of the said Application are false and denied. It is humbly submitted that the principles of "extended producer responsibility" are misconstrued and the same may not be considered. The SWM Rules, 2016 are not applicable to manufacturers/

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brand owners of condoms. The Respondent No. 13 cannot be held responsible for managing the end waste of the used condoms and cannot be expected to provide a proper disposal method; it is respectfully submitted that the same is not within the jurisdiction of this Hon'ble Tribunal.

31. The contents of Paragraph No. 33 of the said Application are false, baseless and denied. Whilst it is true that it is the responsibility of each person to create awareness about proper disposal of condoms so as to save the environment from pollution, it is not correct to allege that manufacturers of condoms are spending large amounts on marketing and advertising their products but are equally negligent in investing necessary funds in creating awareness about proper disposal of their products. As stated above, the Respondent No. 13 provides instructions (on packets of its products) for safe disposal of used condoms. Further, it is reiterated that this Respondent No. 13 has already collaborated with local authorities and is undertaking social and environmental work as a part of its 'Corporate Social Responsibility' and 'Corporate Environment Responsibility'.

32. As regards the contents of Paragraph No. 34 of the said Application, Respondent No. 13 has been actively involved in several activities as a part of its 'Corporate Social

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Responsibility' and 'Corporate Environment Responsibility', as stated above.

33. The contents of Ground 'A' of the said Application are misconstrued and denied.

34. The contents of Ground 'B' of the said Application are false, misconstrued and vehemently denied. The SWM Rules, 2016 are self-explanatory and not applicable to manufacturers and brand owners of condoms. There is no provision in the SWM Rules, 2016, making it mandatory for manufacturers and brand owners of condoms to provide pouches or wrappers with distinctive outward appearance for disposal of used condoms.

35. The contents of Grounds 'C', 'D', 'E' and 'F'of the said Application appear to be generally true and correct. The Respondent authorities have failed in carrying out their responsibilities as envisaged under the Environment Protection Act, 1986 and the SWM Rules, 2016.

36. The contents of Ground 'G' of the said Application are false, misconstrued and vehemently denied. The Applicants have misconstrued the provisions of Rule 17 of the SWM Rules, 2016. It is respectfully submitted that the said Rule 17 is not at all applicable to this Respondent No. 13.

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37. The contents of Ground 'H' of the said Application are false, misconstrued and vehemently denied. The term "waste generator" is clearly defined in Rule 3 (56) of the SWM Rules, 2016. The opinion of the Applicants that the concept of waste generator is to be construed in a wider sense which includes not only users but also the manufacturers is absolutely flawed and not tenable in the eyes of law.

38. The contents of Ground 'I' of the said Application appear to be generally true and correct. The Respondent authorities must perform their duties and responsibilities as contemplated in the SWM Rules, 2016.

39. The contents of Ground 'J' of the said Application are repetitive, false, misconstrued and vehemently denied. The Applicants have misconstrued the provisions of Rule 17 of the SWM Rules, 2016. It is respectfully submitted that the said Rule 17 is not at all applicable to manufacturers and brand owners of condoms, including this Respondent No. 13. The question of violating the said Rule 17 does not arise.

40. It is humbly submitted that there is no cause of action, as alleged. The said Application deserves to be dismissed.

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41. It is further humbly submitted that as regards Prayer Clauses (5) and (6), as sought by the Applicants, this Respondent No. 13 has already been providing instructions in readable font, size and wording (on packets of condoms) for safe disposal of used condoms. There is no mandatory requirement under the SWM Rules, 2016, for the manufacturers of condoms to provide a pouch or wrapper for disposal of each condom with each packet of the product.

42. It is further humbly submitted that as regards Prayer Clause (7), it can be seen that the Applicants have filed the said Application only to make personal commercial gains by demanding an unreasonable amount of Rs. 1,00,000/- from each of the Respondents. The Applicants are interested in publicity in the print and electronic media and are not actually concerned about the environment. The *mala fide* intention of the said Applicants can be clearly seen.

43. There is no merit whatsoever in the said Application and the same deserves to be dismissed by this Hon'ble Tribunal with exemplary costs.

For TTK HEALTHCARE LIMITED

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44. The Respondent No. 13 craves leave to narrate better particulars, if the need so arises. The Respondent No. 13 also craves leave to produce, refer to and rely upon additional documents, if required.

Solemnly affirmed on this 22nd day of November 2021 at Chennai.

For TTK HEALTHCARE LIMITED

Authorised Signatory

Respondent No. 13

Advocate for Respondent No. 13

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22/11/2021

R. GOPINATH, B.A., B.L.,
ADVOCATE & NOTARY PUBLIC
No.131, Kutchery Road, Block - 3,
Flat No.3, Ganapathy Colony, Mylapore,
Chennai - 600 004. Cell : 9500063825

Verification

I, Brijj Balaji Singh, age:54 years, occupation: service, office at:6, Cathedral Road, Chennai 600086, the director/ authorized signatory of Respondent no. 13above named, do hereby verify all the contents of Paragraph Nos. 1 to 44above as the same are true and correct and I state that no material fact has been concealed therein.

For TTK HEALTHCARE LIMITED

Authorised Signatory

Place: Chennai.

Date: 22nd November 2021.

Respondent no. 13

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NOTARY CERTIFICATE

Be it Known and made manifest (Unto all people) that on 22nd Day of November 2021 at Chennai

I, R.GOPINATH Advocate, Notary Appointed by the Government of India to practice in Chennai City State of Tamilnadu duly authorized admitted and sworn subject to the provisions of the Notaries Act 1952(53 of 1952) and Notary Rules 1956, do hereby Certify that

Mr. Brijj Balaji Singh Authorised Signatory of TTK HealthCare Limited personally appeared before me, known to be the person/persons described in the Affidavit in reply by the Respondent No.13, (TTK Healthcare Limited) in O.A.No.56/2018.

The said Mr. Brijj Balaji Singh deposed in my presence and singed his after knowing the content of this Affidavit in reply by the Respondent No.13, (TTK Healthcare Limited) in O.A.No.56/2018 having been read over and explained to the deponent who seemed perfectly to understand it or acknowledged that he signed the same at free will.

This instrument is indented to take effect within Tamilnadu NOTARIAL REGISTER BOOK 1 VOLUME 1 PAGE NO. 33 SERIAL NO. 228

AFFIRMED UNDER SECTION 3(2) (B) of the Acts of Act (44/69)

In Testimony whereof I have hereunto set my hand and seal of office

at Chennai on 22/11/2021

R.GOPINATH ADVOCATE

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ANNEXURE -1

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Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973
Dated : 26-MAR-2019

File No. : SZ/MD/2018/000017

M/s TTK Healthcare Limited,
No.6, Cathedral Road, Chennai,Tamil Nadu,
India
Chennai, Chennai, Tamil Nadu (India) -
600086
Telephone No.: 04428116108 FAX:
04428116387

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/MD/2019/000047 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

TTK'S
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6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

Yours faithfully

S ESWARA REDDY
Licensing Authority

Seal/Stamp

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सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2019/000047

1. M/s TTK Healthcare Limited, No.6, Cathedral Road, Chennai,Tamil Nadu, IndiaChennai, Chennai, Tamil Nadu (India) - 600086 Telephone No.: 04428116108 FAX: 04428116387 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s TTK Healthcare Limited (Protective Devices Division), No.12, K P Natham Road, Thiruvandarkoil, Puducherry, Pondicherry, Puducherry (India) - 605102 Telephone No.: 044-42008218 FAX: 044-28117150.

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:1. Natural Rubber Latex Male Condoms (for both Domestic and Export) Model No.:NIL Intended Use:To avoid unwanted pregnancy and prevention of transmission of sexually transmitted infections (STI). Class of medical device:Class C Material of construction:Natural Rubber Latex Dimension(if any):Length : minimum 180 mm for 53 + or - 2 mm width, / Length: minimum 170 mm for 49+ or -2 mm width Shelflife:Domestic - 3 Years / Export - 5 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIRODH, DELUXE NIRODH, AASHA NIRODH, MASTI, SKORE, DUREX, KOHINOOR, DUREX KOHINOOR, BULK UNTESTED / TESTED CONDOMS, BULK FOILED GENERIC CONDOMS, JEITO, DOM, UNFPA, CONTEX, CHOICE, CONDOMIZE, DOCTISSIMO, MASIBAMBISANE, SUSTAIN NATURAL, INTIMY, MORE A MORE, ETOS, KURIDVAT,. RING SAFE N SURE, TRUST, PRUDENCE, DELIGHT, ULINZI

S ESWARA REDDY

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2	Generic Name:Natural Rubber Latex Male Condoms with 5% Benzocaine as desensitizier (Cream/Solution) for both Domestic and Export Model No.:NIL Intended Use:The male Latex condom lubricated with Benzocaine 5% is intended to be used for contraceptive and prophylactic purposes. Additionally, the lubricant on the condom helps in temporarily prolonging the time until ejaculation. Class of medical device:Class D Material of construction:Natural Rubber Latex and Natural Rubber Latex condom dosed with 5% Benzocaine Dimension(if any):Length minimum 180 mm for 53 + or - 2 mm width, Length 170 mm for 49+ or -2 mm width Shelflife:Domestic - 3 Years / Export - 5 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SKORE, DUREX, DOM, MASTI, KOHINOOR, DUREX KOHINOOR, TRUST, PRUDENCE, DELIGHT, ULINZI, JEITO

Place:

Date26-Mar-19

S ESWARA REDDY

Central Licensing Authority

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F. No. FSC/MD/2019/30

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Device Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002
Dated: 12 JUN 2019

To,

M/s. TTK Healthcare Limited,
(Protective Device Division)
No. 12, KP Natham Road,
Thiruvandarkoil,
Puducherry (India) - 605102

Subject: Issue of Free Sale Certificate of Medical Devices for export purpose-reg.

Sir,

This is with reference to your letter dated 30.03.2019 received by this office vide dairy no. 4326 dated 08.04.2019 and subsequent query reply received vide dairy no. 6650 dated 28/05/2019 on the subject matter.

The Free Sale Certificate no. FSC/MD/2019/37 with respect to medical devices under manufacturing license no. MFG/MD/2019/000047 dated 26.03.2019 is enclosed herewith.

Yours Sincerely

(Dr. V.G. Somani)
Joint Drugs Controller (I)

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F. No. FSC/MD/2019/30

GOVERNMENT OF INDIA
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH AND FAMILY WELFARE

FREE SALE CERTIFICATE

FSC No. FSC/MD/2019/37 **Dated:** 12 JUN 2019

This is to certify that **M/s. TTK Healthcare Limited, (Protective Device Division), No. 12, KP Natham Road, Thiruvandarkoil, Puducherry (India) - 605102** is holding Manufacturing License in Form MD-9 bearing no. MFG/MD/2019/000047 dated 26.03.2019. Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian law and for export as per law of importing country (ies):- Name of the products with their Generic name, Brand name if any mentioned below:

S.No.	Product Name	Brand Name
1.	Natural Rubber Latex Male Condoms	SKORE, DUREX
2.	Natural Rubber Latex Male Condoms with 5% Benzocaine as desensitizer	SKORE, DUREX

(Dr. V.G. Somani)
Joint Drugs Controller (I)

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U.S. FOOD & DRUG ADMINISTRATION

April 15, 2021

TTK Healthcare Limited
Daniel J. S.
Head - Corporate RA/QA [Medical Devices]
Protective Devices Division
6, Cathedral Road
Chennai, Tamil Nadu 600086
INDIA

Re: K202403
Trade/Device Name: SKORE (Colors & Flavors), SKORE (Colors)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 15, 2021
Received: March 19, 2021

Dear Daniel S.:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

bsi.

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 701506**

Issued To: **TTK Healthcare Limited**
Protective Devices Division
No.6, Cathedral Road
Chennai
Tamil Nadu
600 086
India

In respect of:

The design, development and manufacture of smooth, textured, coloured and flavoured natural rubber latex male condoms.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-11-01** Date: **2020-11-11** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 701506

Issued To:

TTK Healthcare Limited
Protective Devices Division
No.6, Cathedral Road
Chennai
Tamil Nadu
600 086
India

NBOG code(s)	Device description	Intended purpose
Class IIb		
SMD0107	Natural Rubber Latex Condoms	For contraception and prevention of Sexually Transmitted Diseases

First Issued: **2018-11-01** Date: **2020-11-11** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 701506**

Date: **2020-11-11**

Issued To: **TTK Healthcare Limited**
Protective Devices Division
No.6, Cathedral Road
Chennai
Tamil Nadu
600 086
India

Subcontractor:	Service(s) supplied
CEpartner4U BV Esdoornlaan 13 3951 DB Maarn The Netherlands	**EU Representative**
TTK Healthcare Limited Protective Devices Division Research and Development No3, Thiruneermalai Main Road Chrompet Chennai Tamil Nadu 600 044 India	**Design** **Packaging** **Testing**
TTK Healthcare Limited Protective Devices Division No 12, K P Natham Road Thiruvandar Koil Puducherry 605 102 India	**Manufacture**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

TTK Healthcare Limited
Protective Devices Division
No.6, Cathedral Road
Chennai 600 086
Tamil Nadu
India

Holds Certificate No: **FM 22435**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

I. The Design, Development, Manufacturing, Marketing and Despatch of:
a. Natural Rubber Latex Male Condoms, b. Natural Rubber Latex Male Condoms with Benzocaine, c. Synthetic Male Condoms, d. Natural Rubber Latex Male Condoms with GTN Gel;
II. Design, Development, Procurement and Despatch of Personal lubricants;
III. Procurement and Despatch of Vibratory Rings.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 1992-12-14
Latest Revision Date: 2020-11-16

Effective Date: 2020-11-02
Expiry Date: 2023-11-01

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Certificate No: **FM 22435**

Location	Registered Activities
TTK Healthcare Limited Protective Devices Division No.6, Cathedral Road Chennai 600 086 Tamil Nadu India	Marketing of Natural Rubber Latex Male Condoms, Synthetic Male Condoms, Natural Rubber Latex Male Condoms with Benzocaine, Natural Rubber Latex Male Condoms with GTN Gel, Personal lubricants and Vibratory Rings.
TTK Healthcare Limited Protective Devices Division No.12, K P Natham Road Thiruvandar Koil 605 102 Puducherry India	I. The Manufacturing and Despatch of Natural Rubber Latex Male Condoms and Natural Rubber Latex Male Condoms with Benzocaine II. The Testing, Foiling, Packing and Despatch of Synthetic Male Condoms: III. Procurement and Despatch of Personal lubricants and Vibratory Rings.
TTK Healthcare Limited Protective Devices Division No. 3, Thiruneermalai Main Road Chrompet Chennai 600 044 Tamil Nadu India	I. The Design, Development, Testing, Foiling, Packing and Despatch of Natural Rubber Latex Male Condoms and Synthetic Male Condoms II. The Design and Development of Natural Rubber Latex Male Condoms with Benzocaine III. The Design, Development, Foiling, Packing and Despatch of Natural Rubber Latex Male Condoms with GTN Gel. IV. The Design, Development and Despatch of Personal lubricants.

Original Registration Date: 1992-12-14
Latest Revision Date: 2020-11-16

Effective Date: 2020-11-02
Expiry Date: 2023-11-01

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SCS Global Services *does hereby certify that an independent audit has been completed and conformity to the applicable standard(s) has been confirmed for:*

TTK Healthcare Limited - Protective Devices Division

No.6, Cathedral Road, Chennai, Tamil Nadu, 600086, India
No. 12, KP Natham Road, Thiruvandar Koil, 605102 Puducherry, India

This single chain of custody certificate covers the production of male condoms using the transfer system.

The facility(s) are hereby Chain of Custody certified to sell products as:

FSC 100%

The assessment has been conducted by SCS Global Services in accordance with the protocols of the Forest Stewardship Council® A.C. (FSC®).

FSC Standard: FSC-STD-40-004 V3-0; FSC-STD-50-001 V2-0

Certificate Code: SCS-COC-005152 Trademark License Code: FSC-C123915

Valid from: 9 January 2020 Expiry date: 8 January 2025

FSC
www.fsc.org
FSC® A000521

The mark of responsible forestry

RESPONSIBLE FORESTRY CERTIFIED SCS GLOBAL SERVICES

SCSglobal SERVICES

Sarah Harris, Managing Director
SCS Global Services
2000 Powell Street, Ste. 600, Emeryville, CA 94608 USA

Printed: 8 Jan, 2020

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

TTK Healthcare Limited
Protective Devices Division
No.6, Cathedral Road
Chennai 600 086
Tamil Nadu
India

Holds Certificate No: **MD 72364**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

I. The Design, Development, Manufacturing and Distribution of:
a) Natural Rubber Latex Male Condoms,
b) Natural Rubber Latex Male Condoms with Benzocaine,
c) Natural Rubber Latex Male Condoms with GTN Gel &
d) Synthetic Male Condoms
II. Design, Development, Procurement and Distribution of Personal lubricants.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-03-09
Effective Date: 2020-11-25
Latest Revision Date: 2020-11-25
Expiry Date: 2023-11-24

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Certificate No: **MD 72364**

Location	Registered Activities
TTK Healthcare Limited Protective Devices Division No.6, Cathedral Road Chennai Tamil Nadu 600 086 India	Marketing of, i. Natural Rubber Latex Male Condoms, ii. Synthetic Male Condoms, iii. Natural Rubber Latex Male Condoms with Benzocaine, iv. Natural Rubber Latex Male Condoms with GTN Gel and v. Personal lubricants.
TTK Healthcare Limited Protective Devices Division No. 12, K P Natham Road Thiruvandar Koil 605 102 Puducherry India	I. The Manufacturing and Distribution of Natural Rubber Latex Male Condoms and Natural Rubber Latex Male Condoms with Benzocaine II. The Testing, Foiling, Packing and Distribution of Synthetic Male Condoms.
TTK Healthcare Limited Protective Devices Division No. 3, Thiruneermalai Main Road Chrompet Chennai 600 044 Tamil Nadu India	I. The Design and Development of Natural Rubber Latex Male Condoms and Synthetic Male Condoms II. The Design and Development of Natural Rubber Latex Male Condoms with Benzocaine III. The Design, Development, Testing, Foiling, Packing and Distribution of Natural Rubber Latex Male Condoms with GTN Gel. IV. The Design, Development and Distribution of Personal lubricants.

Original Registration Date: 2004-03-09
Latest Revision Date: 2020-11-25

Effective Date: 2020-11-25
Expiry Date: 2023-11-24

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Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

TTK Healthcare Limited
Protective Devices Division
No.12, K P Natham Road
Thiruvandar Koil 605 102
Puducherry
India

Holds Certificate No: **EMS 682846**

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

I. The Design, Development, Manufacturing, Marketing and Despatch of:
a. Natural Rubber Latex Male Condoms, b. Natural Rubber Latex Male Condoms with Benzocaine, c. Synthetic Male Condoms, d. Natural Rubber Latex Male Condoms with GTN Gel;
II. Design, Development, Procurement and Despatch of Personal lubricants;
III. Procurement and Despatch of Vibratory Rings.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2012-04-24
Latest Revision Date: 2020-11-16

Effective Date: 2020-11-02
Expiry Date: 2023-11-01

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Certificate No: **EMS 682846**

Location	Registered Activities
TTK Healthcare Limited Protective Devices Division No.12, K P Natham Road Thiruvandar Koil 605 102 Puducherry India	I. The Manufacturing and Despatch of Natural Rubber Latex Male Condoms and Natural Rubber Latex Male Condoms with Benzocaine II. The Testing, Foiling, Packing and Despatch of Synthetic Male Condoms: III. Procurement and Despatch of Personal lubricants and Vibratory Rings.
TTK Healthcare Limited Protective Devices Division No. 3, Thiruneermalai Main Road Chrompet Chennai 600 044 Tamil Nadu India	I. The Design, Development, Testing, Foiling, Packing and Despatch of Natural Rubber Latex Male Condoms and Synthetic Male Condoms II. The Design and Development of Natural Rubber Latex Male Condoms with Benzocaine III. The Design, Development, Foiling, Packing and Despatch of Natural Rubber Latex Male Condoms with GTN Gel. IV. The Design, Development and Despatch of Personal lubricants.

Original Registration Date: 2012-04-24
Latest Revision Date: 2020-11-16

Effective Date: 2020-11-02
Expiry Date: 2023-11-01

bsi.

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Certificate of Registration

OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM - ISO 45001:2018

This is to certify that:

TTK Healthcare Limited
Protective Devices Division
No.12, K P Natham Road
Thiruvandar Koil 605 102
Puducherry
India

Holds Certificate No: **OHS 682847**

and operates an Occupational Health and Safety Management System which complies with the requirements of ISO 45001:2018 for the following scope:

I. The Design, Development, Manufacturing, Marketing and Despatch of:
a. Natural Rubber Latex Male Condoms, b. Natural Rubber Latex Male Condoms with Benzocaine, c. Synthetic Male Condoms, d. Natural Rubber Latex Male Condoms with GTN Gel;
II. Design, Development, Procurement and Despatch of Personal lubricants;
III. Procurement and Despatch of Vibratory Rings.

[Previously certified to BS OHSAS 18001:2007 since 20-04-2009]

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2019-11-07
Latest Revision Date: 2020-11-16

Effective Date: 2020-11-02
Expiry Date: 2023-11-01

ANAB ACCREDITED MANAGEMENT SYSTEMS CERTIFICATION BODY

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Certificate No: **OHS 682847**

Location	Registered Activities
TTK Healthcare Limited Protective Devices Division No.12, K P Natham Road Thiruvandar Koil 605 102 Puducherry India	I. The Manufacturing and Despatch of Natural Rubber Latex Male Condoms and Natural Rubber Latex Male Condoms with Benzocaine II. The Testing, Foiling, Packing and Despatch of Synthetic Male Condoms: III. Procurement and Despatch of Personal lubricants and Vibratory Rings.
TTK Healthcare Limited Protective Devices Division No. 3, Thiruneermalai Main Road Chrompet Chennai 600 044 Tamil Nadu India	I. The Design, Development, Testing, Foiling, Packing and Despatch of Natural Rubber Latex Male Condoms and Synthetic Male Condoms II. The Design and Development of Natural Rubber Latex Male Condoms with Benzocaine III. The Design, Development, Foiling, Packing and Despatch of Natural Rubber Latex Male Condoms with GTN Gel. IV. The Design, Development and Despatch of Personal lubricants.

Original Registration Date: 2019-11-07
Latest Revision Date: 2020-11-16

Effective Date: 2020-11-02
Expiry Date: 2023-11-01

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SABS

Permit to Apply Certification Mark

Subject to the provisions of the Standards Act, 2008 (Act 8 of 2008), the relevant regulations made thereunder and the permit conditions contained in the under mentioned schedules, this permit authorizes

TTK HEALTHCARE LIMITED - PROTECTIVE DEVICES DIVISION (FORMERLY TTK PROTECTIVE DEVICES LIMITED)
Co Reg. L24231TN1958PLC003647
PUDUCHERRY 605 102, INDIA

to apply the certification mark

SABS APPROVED

in respect of the mark specification

SANS 4074:2017
TO: NATURAL RUBBER LATEX MALE CONDOMS - REQUIREMENTS AND TEST METHODS

This permit, including the schedules 1 to 3 which form an integral part thereof:
- is issued without alteration;
- is identified by the applicable permit number;
- is subject to any condition or limitation contained therein;
- is valid subject to ongoing compliance with permit conditions;
- bears the embossed SABS Commercial seal. In the absence of the seal, the permit and the schedules shall be invalid; and
- the permit may be authenticated by referring to the register of "Certified Clients" on the SABS Commercial website (www.sabs.co.za)
- Scheme Type 5 permit applies to products that have been tested.

Permit Number	5221/7608
Effective Date	31 May 2021
Expiry Date	02 July 2023
Date of Original Registration	08 December 1995
Chief Executive Officer	

sanas

C07a

SABS COMMERCIAL SOC Ltd
1 Dr Lategan Rd, Groenkloof, Pretoria
Republic of South Africa

A4A1005120

01/R10

TTK'S CONFIDENTIAL

UNFPA/WHO Prequalification Scheme for Male Latex Condom

Prequalification Status Notification

Copenhagen, 25 September 2020

Dear Brijj Balaji Singh

RE: MC22-19 TTK Healthcare, Protective Devices Division

Following the UNFPA prequalification inspection of TTK Healthcare, Protective Devices Division on May 14 – 16, 2019, the corrective actions observed and listed in the inspection report have been reviewed by technical experts. The corrective actions have been found to be acceptable and will be verified during the next inspection.

This letter[1], therefore, serves as a confirmation that the male latex condom factory located at No. 12, KP Natham Road, Thiruvandar Koil, Puducherry 605 102, India, has attained WHO/UNFPA Prequalified status as of 25 September 2020.

This factory and the prequalified products will be listed on the UNFPA and WHO websites. The website list always reflects the most recent prequalification information, while this letter only serves as notification of prequalification on 25 September 2020. As described in the guidelines for the WHO/UNFPA prequalification scheme, factories will be re-inspected every third year (i.e. the next inspection will be in 2022). During this period, the factory is obligated to notify UNFPA of any major changes in, but not limited to, production premises; production and testing equipment; senior management; certifications or licenses; product recalls; reports of adverse events; product design; specification of raw materials; packaging and new information on shelf life. For further and complete information please go to www.unfpaprocurement.org/prequalification-programme

Please do not hesitate to contact the Prequalification Team at psb.prequalification@unfpa.org should you require further information regarding prequalification.

Yours sincerely

DocuSigned by:
Seloi Mogatle
4184BA9DC706474...

Seloi Mogatle
Technical Specialist
Procurement Services Branch
United Nations Population Fund

[1] This letter is only confirming the current pre-qualification status of the factory at the time of issue. It shall not be seen as a certificate, diploma or legal document. The letter shall not be used for advertisement purposes. Those seeking to verify the factory's current prequalification status should refer to UNFPA's website (https://www.unfpa.org/resources/prequalification-programme-male-latex-condoms)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 20, 2014

TTK Protective Devices Limited
% Manoj Zacharias
Consultant
Liberty Management Group, Ltd.
2871 Coastal Drive
Aurora, IL 60503

Re: K132490
Trade/Device Name: SKORE Natural
SKORE Dots Natural
SKORE Bulbous Natural
SKORE Bulbous Dots & Ribs Natural
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
Dated: September 1, 2014
Received: September 9, 2014

Dear Manoj Zacharias,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

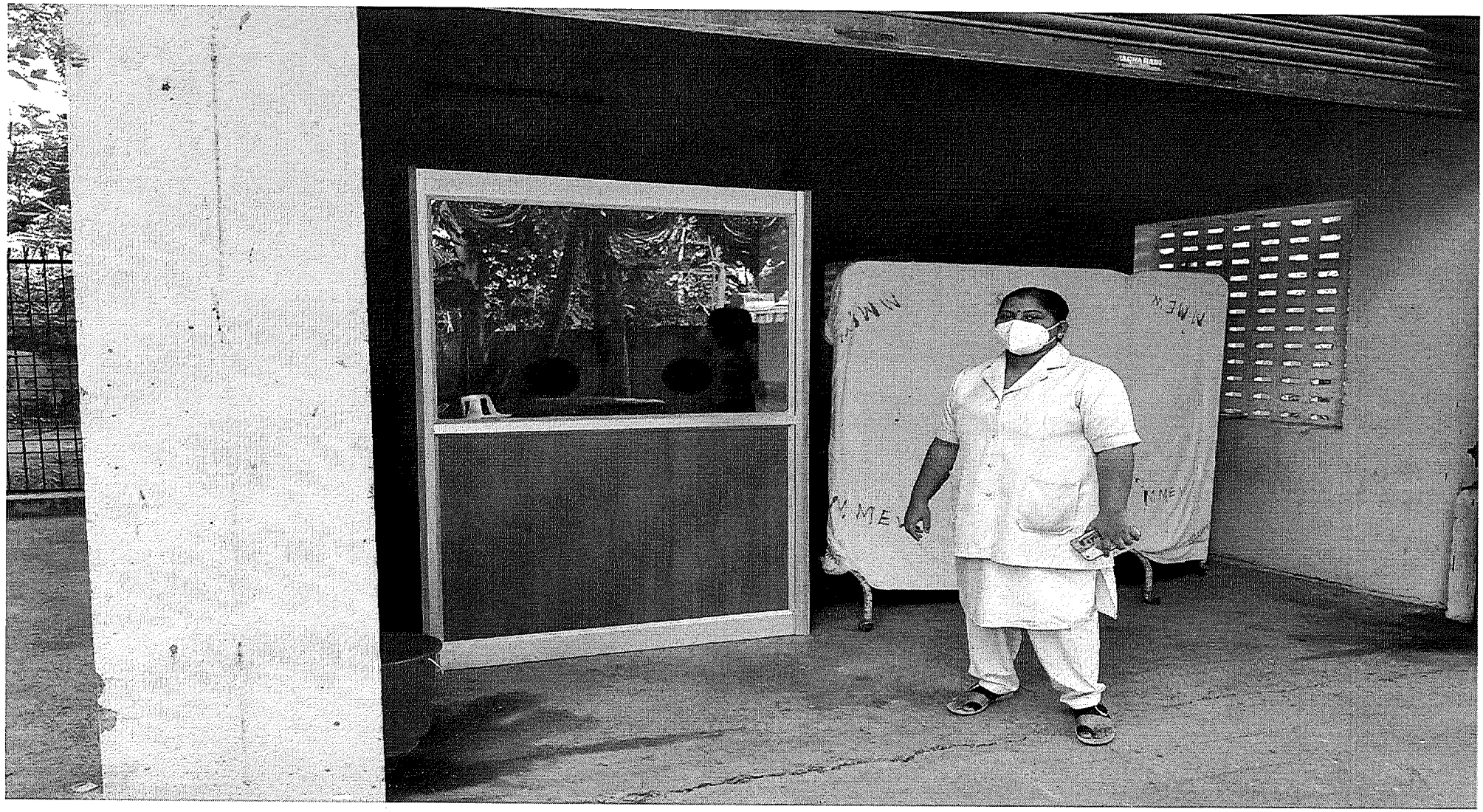
Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

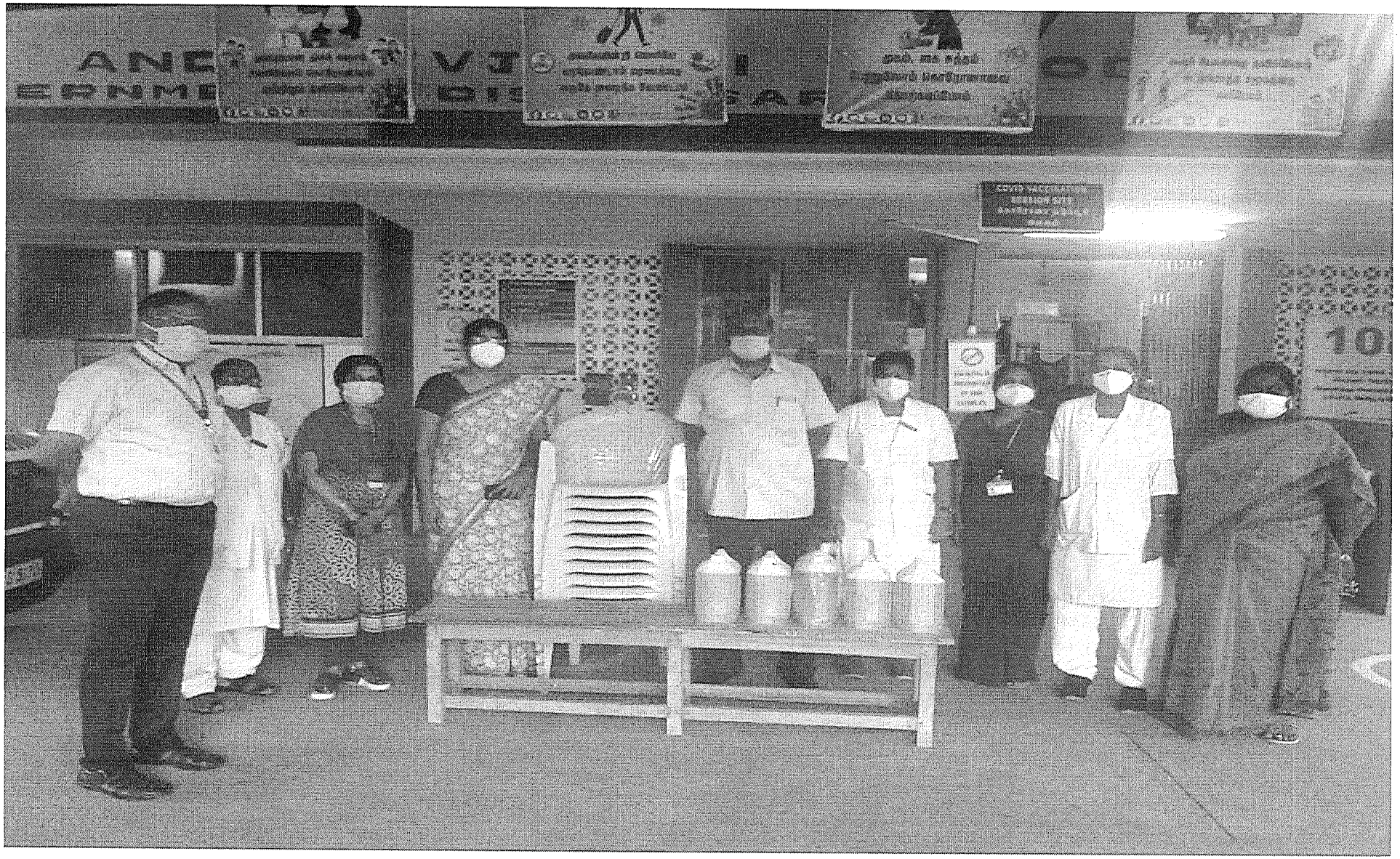
Thirubhuvanai PHC - As part of CSR Activity provided with COVID Shield Standing rack on Sep - 2020



ANNEXURE-2 230

Ariyur PHC - As Part of CSR Activity provided with Chairs

& Sanitizers on June - 2021



Ambulance facility provided to PH for COVID 19 from Oct 2020 to Jan 2021

GOVERNMENT OF PUDUCHERRY
DIRECTORATE OF HEALTH AND FAMILY WELFARE SERVICES, PUDUCHERRY

No. 682/DD(Imm)/2020

Date : 07.10.2020

OFFICE MEMORANDUM

Sub: DHFWS - Mapping of ambulances with industries/factories to the Directorate of Health & Family Welfare Services, Puducherry - Orders - Issued.

Ref: Order No. 1703/DRDM/DM/D2/2020/109 dated 01.10.2020 of Spl.Secretary to Govt. (Relief & Rehabilitation) - cum - District Collector, Puducherry

As per the Instructions of District Collector under Disaster Management Act 2005 your ambulance with Driver have been positioned at PHC Mudaliarpet under the control of Medical Officer I/C of PHC Mudaliarpet.

The Ambulance has been utilized for shifting the COVID-19 patients of PHC Mudaliarpet service area and nearby PHC service area under the control of Medical Officer I/C of PHC Mudaliarpet.

The Office of DOHFWS expresses thanks for your co-ordination in taking COVID-19 pandemic.

(Dr. M.Murugan)
Medical Officer
O/o Dy Director (Imm)

To
The Asst. General Manager - Operations
TTK Health care Ltd,
Thiruvandarkoil, Puducherry

Copy submitted to:
1. The District Collector-cum-Secretary (Health), Puducherry
2. The Director (Health), DHFWS, Puducherry.
3. The Deputy Director (PH), DHFWS, Puducherry.
4. The OSD, COVID-19 War room, EOC
5. The Director, Dept. Of Industries and Commerce, Puducherry

Corporate Social Responsibility

1. Runs Voluntary Blood Banks at Chennai & Bangalore .

2. Runs De-addiction centre in Chennai for Alcholics & Drug addicts.

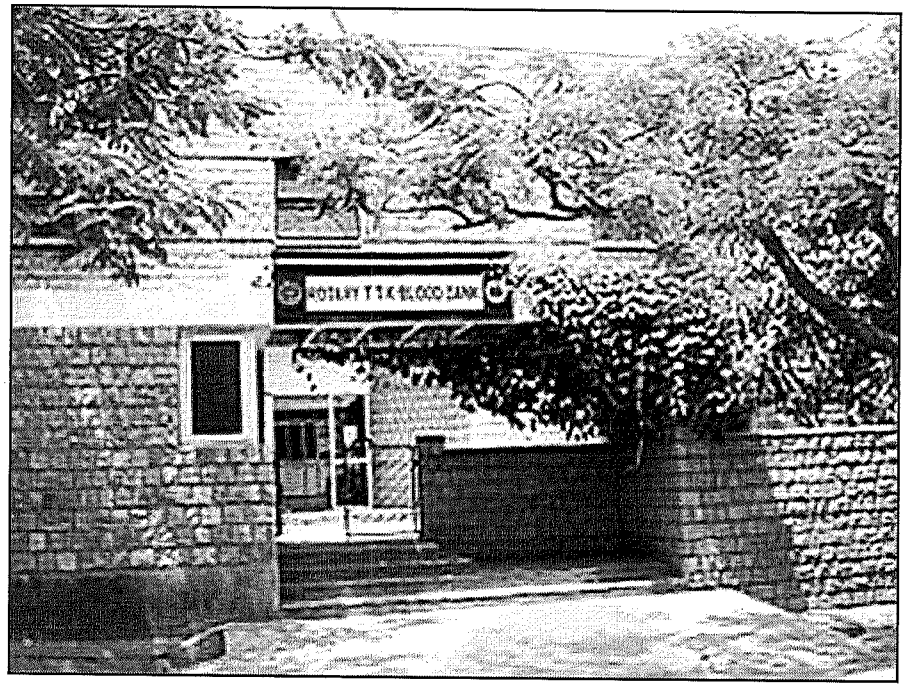
3. Runs school at Manjakudi Village in Tiruvarur District.

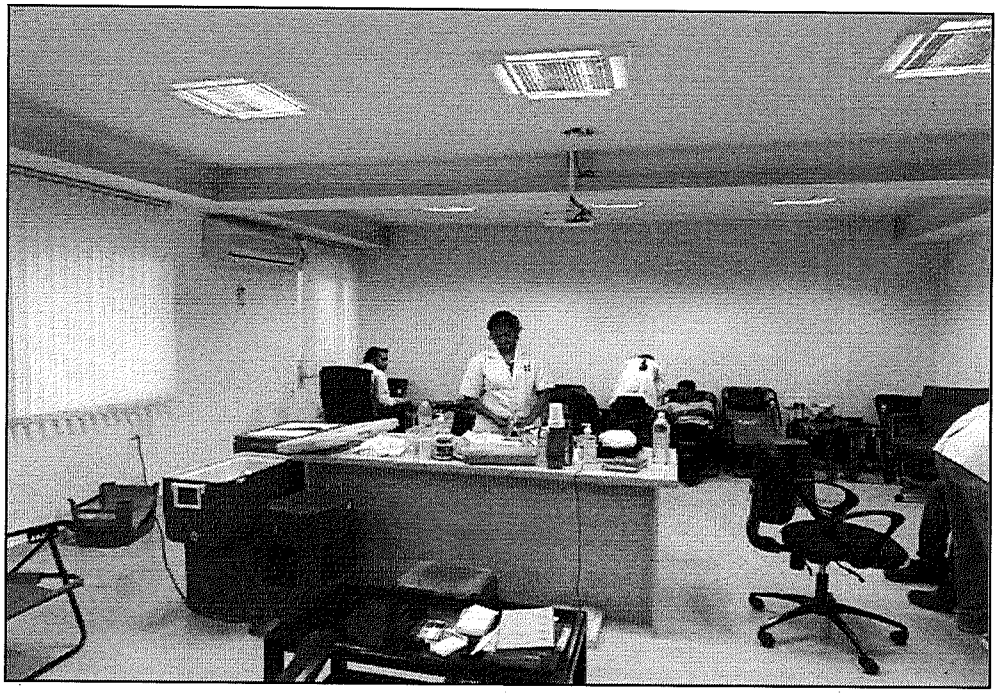
4. Contribution to Environment – Greenbelt development in Virudhunagar.

Corporate Social Responsibility

TTK has always made active contributions to social development.

Runs voluntary Blood Banks at Chennai and Bangalore with the latest equipments.





Corporate Social Responsibility

Runs the premier de-addiction centre in Chennai for alcoholics and drugs addicts.

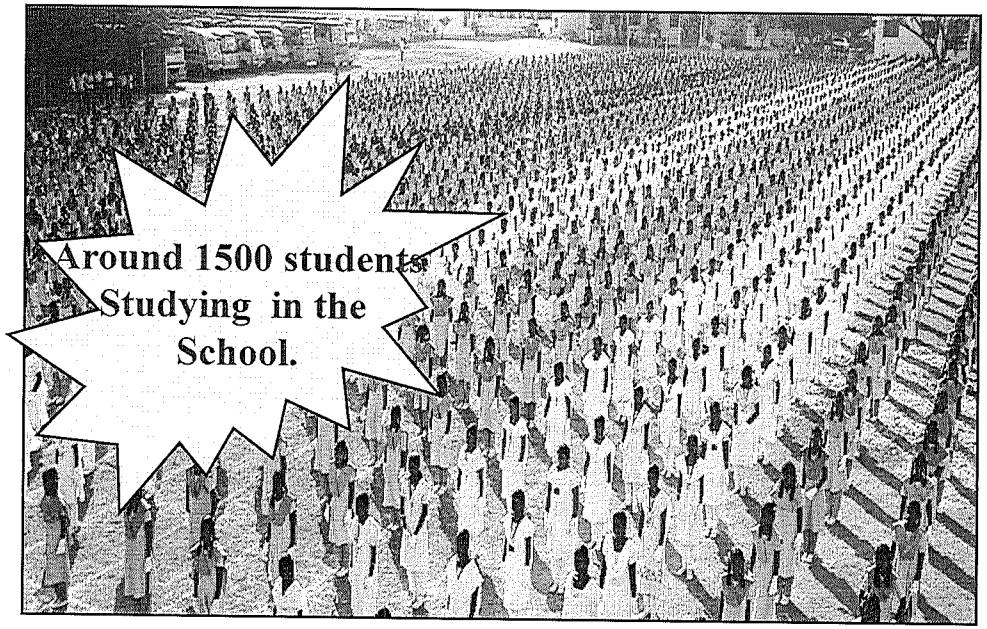
Conducts regular AIDS awareness programs.

Takes active interest in the Indian Cancer society.

Corporate Social Responsibility

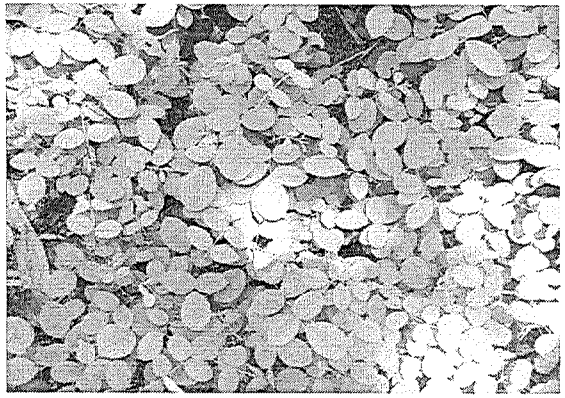
Supporting Educational Institute.

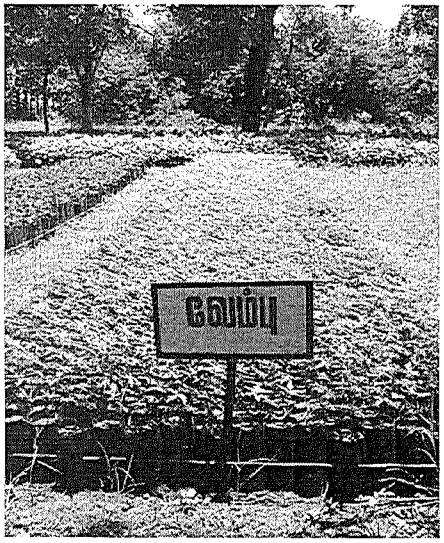
TT Narasimhan Swami Dayananda Higher Secondary School, Manjakkudi, Tiruvarur

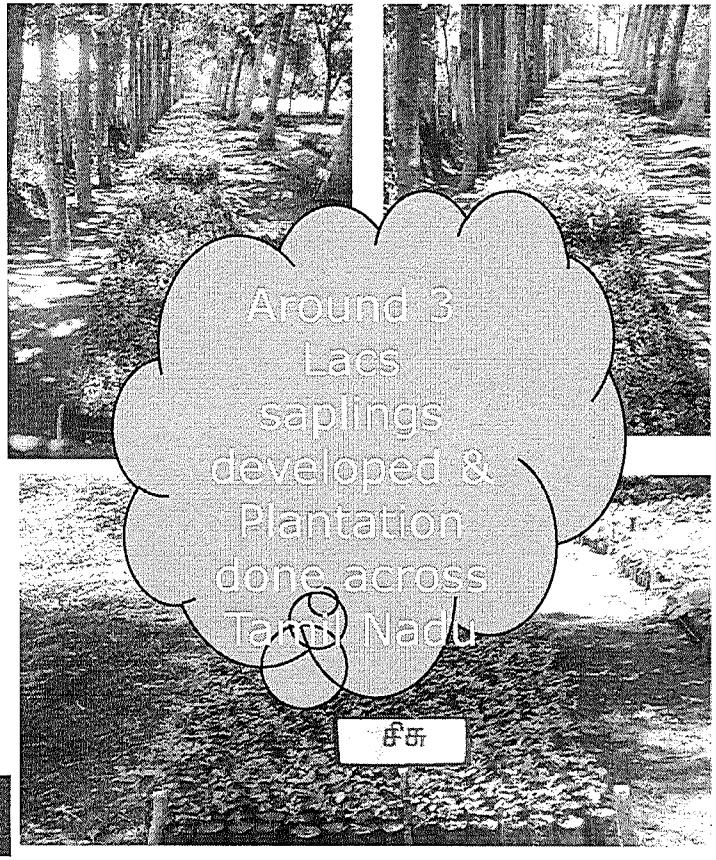


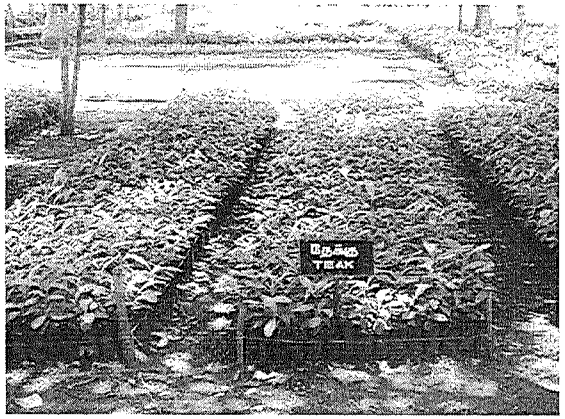
Contribution to Environment

Global expansion of Greenbelt development









View of our Nursery at Well site – Virudhunagar