TERMS OF REFERENCE FOR THE R&D PROJECT

[Technical Textiles for Medtech Applications Sectional Committee TXD 36 under Textiles Department of BIS]

1) **Title of the project:** — Study of safety, performance and constructional requirement for surgical sutures (absorbable and non-absorbable)

2) **Background:-**

2.1 Surgical sutures are used to close wounds and aid in tissue healing in a variety of different surgical procedures such as orthopaedic, cardiovascular, alimentary, ophthalmic, laparoscopic, and other surgical procedures. Surgical sutures are helpful to reduce post-operative discomfort, shorten hospital stays, and expedite patient recovery. Based on application and material, there are different varieties and size of surgical sutures for natural or synthetic textiles, single filament or multifilament or braided or twisted with or without a coating.

2.2 Surgical sutures are being manufactured in India as well as being imported, however there is no Indian standard on the subject. In absence of Indian Standard, majority of the stakeholders are following either United States Pharmacopeia (USP) or British Pharmacopeia (BP) or European Pharmacopeia. So, it becomes important to study safety, performance, and constructional parameters of surgical sutures for deciding the appropriate requirement in Indian context.

2.3 The outcome of this R &D project will serve as basis for developing Indian Standard on the subject which will ensure consumer protection and safeguard public health.

3) **Objective**

To collect the technical data and scientific evidence for safety, performance and constructional requirement of surgical sutures (absorbable and non-absorbable) from primary and secondary sources.

4) **Scope: -**

a) Undertake study and analyse the existing literature which include but not restricted to the following :-

- International standard and regulation,
- Journals and research papers,
- Standard operating procedures (SOPs)/guidelines of Ministry/regulator/users,
- Studies/research conducted by any organization
- Any other relevant published information.

b) Collection of the database for manufacturers (small, medium and large-scale), testing infrastructure and users in the country.

c) Collection of import and export data, type of standards and regulation being followed by domestic/foreign manufacturers, comparative analysis of these standards and regulation.
d) Undertake 2 visits to each of small, medium and large-scale manufacturer and collect the information on the following aspects :-

i) Types of raw material being used
ii) Data/compliance of biocompatible evaluation and other requirement for each type of raw material
iii) Manufacturing process
iv) Good manufacturing practice
v) In-process controls being exercised during manufacturing
vi) Varieties being manufactured
vii) Standards being followed
viii) Testing method being used
ix) Testing infrastructure available
x) Post manufacturing quality/in-house data for safety, performance and constructional parameter for all the varieties being manufactured
xi) Sampling plan being followed
xii) Sterilization method being used
xiii) Marking and labelling of the product
xiv) Packaging and storage conditions
xv) Sustainability practices [sustainable raw material, energy efficient processes and methodologies, renewable energy sources, 3Rs (Reduce, Reuse and Recycle), waste management and disposal mechanisms]
xvi) Focused group discussions with teams involved in production, testing, and R&D to address quality issues, discuss challenges faced, and gather suggestions for improvement

The feedback from other manufacturers (where visit is not carried out) shall be collected by circulating suitable questionnaire covering above information through email or any other digital means.

e) Undertake 2 visits to users (one Govt and one private NABH accredited Hospital) and 2 visits to testing labs (one Govt/ and one private NABL accredited lab) to collect information including but not restricted to the following: -

User

i) Standards and regulations being followed
ii) Compliance mechanism being followed (test certificate from supplier, third party testing)
iii) Focused group discussion on quality issues, challenges being faced and suggestions if any.

Lab

i) Standards and regulation being followed
ii) Testing methods being followed
iii) Testing infrastructure
iv) Focused group discussion on testing related issues, challenges being faced and suggestion

The feedback from other hospitals (Govt and private NABH accredited) and labs (Govt and private NABL accredited) where visit is not carried out shall be obtained through suitable questionnaire covering above information.

f) Collection of 2 samples from each from large, medium and small-scale industries of each variety of surgical sutures and carry out testing from 2 NABL accredited lab (1 Govt Lab and 1 Pvt. Lab) for parameters like but not restricted to length, diameter, knot strength/breaking load, needle attachment, extractable color, sterility.

The biocompatibility evaluation data for each type of material used shall be collected from the manufacturers .

g) Preparation of a comprehensive project report covering all the above information.

5) Research Methodology: -

a) Collect and analyse the data/information as specified in the scope [4 (a), (b) and (c)].
b) Visit manufacturers, users and labs and collect data/information as specified in the scope [4 (d) and (e)].
c) Collect and test the samples as specified in the scope 4 (f).
d) Analysis the data/information and prepare a comprehensive project report.

6) Expected Deliverables: -

a) Comprehensive report in soft/hard form of study covering all the aspects detailed in the scope of the R & D project.
b) Questionnaire feedback, testing report, focussed group discussion report, other relevant documents and information shall be appended to the project report.

7) Requirement for the CVs:-

Graduate in textile technology or textile engineering or textiles chemistry or fibre science and technology or manmade fibre technology or biomedical engineering or post graduate in microbiology.

8) Timeline and Method of progress Review :-

The duration of the project is **120 days** from the date of the award of the project. The stagewise indicative timelines are as follows:-

Indicative Time line	**Method of progress**
0 to 30 days	Literature review, desktop study, collection of data and information

	Note : - The sampling plan for visit and collection of samples shall be discussed and finalized with nodal officer after literature survey and desktop research.
31 to 75 days	Visit to manufacturer, user, testing lab Collection of data and information and collection of samples
76 to 105 days	Testing of samples (except long duration test with testing time more than 30 days) preparation and submission of first draft report
106 to 120 days	Submission of the final project report.

9) Support BIS will provide: -

a) All the relevant Indian Standards/ISO Standards or any other standards required during the project will be provided by BIS.
b) Facilitate/introduction of the project leader/organization to relevant Industry and industry association, testing lab, institute, acedamia, user, regulator/ministries.
c) Facilitate testing of samples in BIS Lab/BIS Recognized Lab.

10) Nodal Point

In case of queries/clarification, Shri Dharmbeer, Scientist D and Member Secretary of TXD 36 may be contacted on txd@bis.gov.in, 011-23231282, 9910825544.