TERMS OF REFERENCE FOR THE R&D PROJECT

[Surgical Instruments Sectional Committee MHD 01]

1. **Title**: Methodology for performance evaluation of Laparoscopic Devices

2. **Background:**

With the advent of modern surgical techniques, minimally invasive surgery (*Otherwise called key hole surgery or Laparoscopic surgery*) has grown importance because of the speeder recovery time. Survey shows that the causes of malfunctions in the laparoscopic devices were leading to serious consequences in the patients. It is important that the standard test methods are defined for safe use of laparoscopic devices.

3. **Objective:**

The Objective of the project is to study and define the test methodology for safety and essential performance evaluation of the laparoscopic devices. The project is intended to extensively study the various product types in the laparoscopic devices and define test methodologies for evaluating the performance of the various categories of laparoscopic devices as follows:

- Handheld instruments,
- Endovision system,
- Insufflator & Irrigation Devices,
- Access devices and
- Energy Devices

4. **Scope:**

4.1 Comprehensive **study of existing literature** which includes international standards, journals, research papers, any SoPs/ guidance/ instructions issued by the Ministries/ regulators concerned and any other study

4.2 Collection of **scale-wise data on manufacturing base** through government sources (websites, reports) or industry associations

4.3 Analysis of the **import and export data** and conduct analytical study of the technical regulations on the product in various countries

4.4 Analytical study on availability of **test facilities** in the country

4.5 Collection of data on the following through visits to 2 large scale industries, total 2 Medium/ Small/ Micro, 1 government and 1 NABL accredited private testing facility:

- Material requirements,
- Manufacturing process,
- Product varieties,
- Electrical safety test requirements,
- Biocompatibility test requirements,
- Sterilization requirements,
- Sampling Plan requirements,
- Performance test methodology and parameters
    - Degree of freedom test, Bench-top testing like cut testing, grasp testing, pull-off testing, ergonomics and usability testing (*for Handheld instruments*)
    - Field of view, Image resolution (*for Endovision system)*,

- Inflation Pressure test, Gas flow test, Gas volume test (*for Insufflator & Irrigation Devices*),
- Penetration/ insertion force test, deflection test (*for Access devices*)
- Tissue effect, Maximum power limit, thermal spread, Maximum temperature limit, Vessel sealing ability test, Insulation test, tissue conductivity testing, Waveform testing, electrode size (*for Energy Devices*)

4.6 User feedback from Surgeons

5. Research Methodology

The project will involve the following research methodologies:

(a) Study the literature and analyse it in respect to the scope

(b) Survey the market through structured questionnaires for collecting data in respect to the scope

(c) Contact the relevant organizations and associations (Industry/ user associations) for gathering the data

(d) Visits to the manufacturing units to collect data as per the scope and observe the following:

1. Manufacturing processes,
2. In-process controls,

(e) Discussion with focused groups (Quality control personnel and person responsible for manufacturing) through structured questionnaires on the test methodologies

(f) Samples to be tested inhouse for functional and safety requirements during the visits to industries. Samples shall be tested in such a manner that there is sufficient data to compare the performance and the range of varieties being manufactured by any particular manufacturer. For this purpose, samples from the lowest, middle, highest range shall be preferably considered for testing. In case of non-availability of samples during the visit or tests are time consuming in nature, the test results of the samples already tested and documented by the manufacturer may be collected for the purpose of analysis.

(g) Comprehensive reporting on all aspects.

6. Delivery Milestones and Review Process:

The duration of the project is 6 months from the date of award of the project. The proposed indicative timeline stage-wise is given below:

- An interim report indicating the review of the literature, desktop research, questionnaire collected and sampling plan shall be submitted in 2 Months from award of the project.
- Draft report shall be submitted by the end of 4 Months from award of the project.
- Final report shall be submitted within 6 Months from award of project, including all the deliverables mentioned in **ITEM 4** and following the **ITEM 5**.

7. Support from BIS:

BIS shall support the project by providing access to Indian standards, international standards, BIS Licensee details, BIS Laboratory details.

8. Nodal Point:

Ms. Nagavarshini M., Scientist B/ Assistant Director, Member Secretary, MHD 01 may be contacted for more clarification on the R&D project (Email address: mhd@bis.gov.in)