TERMS OF REFERENCE FOR THE R&D PROJECT

[Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02 under Medical Equipment and Hospital Planning Department]

1 Title:

Study of general and functional requirements concerning safety and performance of Arthroscopy Systems including the methods of tests.

2 Background:

Arthroscopy systems are essential medical tools used for minimally invasive examination and treatment of joint-related conditions. The R&D project aims to collect extensive data to address quality, safety, interoperability and other technical requirements of arthroscopy system. This will ensure that we are keeping pace with technological advancements, promoting innovation, and fostering national and international trade.

3 Objective:

To collect and analyse the relevant data from primary and secondary sources on variety of arthroscopy systems concerning to their, but not limited to its, manufacturing, quality, safety.

4 Scope:

4.1 To study and carryout a comparative analysis of various types of Arthroscopy System for technical requirements concerning safety & performance.

4.2 The study and comparative analysis shall be based on, but not limited to, the following aspects:

4.2.1 Comprehensive study of existing literature including international standards journals, research papers, any SoPs/ guidance/ best practices/ instructions issued by the Ministries/ regulators related to arthroscopy systems.

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

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

4.2.4 Analysis of availability of test facilities in the country.

4.2.5 Assessment of the current market landscape and collection of user feedbacks pertaining to arthroscopy systems in India and abroad, including product availability and current technological trends.

Gathering insights on the performance and safety requirements and challenges in arthroscopic procedures through collaboration with medical professionals and experts.

Analysis of the unique challenges and requirements for Arthroscopy systems in the Indian healthcare context, considering factors such as patient demographics, healthcare infrastructure, and environmental conditions.

4.2.6 Generation of data regarding technical requirements for arthroscopy systems, concerning its functionality and safety (taking into account *Usability Engineering in Engineering Design*), defining general and specific requirements for arthroscopy systems, encompassing components like scopes, cameras, light sources, and image management systems.

a) Test methods to evaluate the performance, safety, and reliability of arthroscopy systems.

b) Quality control and safety procedures relevant to the manufacture, use, and maintenance *(including Disinfection and Sterilization)* of arthroscopy systems.

5 Research Methodology:

The study will adopt a multi-faceted research approach, including:

5.1 Literature Review: A comprehensive review of existing international standards and practices related to arthroscopy systems concerning safety, quality and essential requirements of components and the system in whole.

5.2 Field Surveys:

5.2.1 Survey the market through structured questionnaires for collecting information in respect to the scope

5.2.2 Visit manufacturing units and understand manufacturing processes, in-process controls and test methods followed by the manufacturers to assess the essential requirements.

Factory Visit plan:

Large Scale: 2 manufacturing units.

Medium / Small / Micro Scale: 2 manufacturing units

Visiting at least two testing laboratories involved in testing of various parameters of Arthroscopy systems one each of the government and NABL accredited private testing laboratory.

Discussion with focused groups (Quality control personnel and person responsible for manufacturing) through structured questionnaires

5.3 Samples to be tested in-house 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.

5.4 Medical Expert Consultations: In-depth interviews and discussions with medical professionals, surgeons, manufacturers and experts in arthroscopy to understand and address the requirements of Arthroscopy system.

The research methodology will involve a combination of desk-based research, surveys, interviews, and expert consultations to ensure a comprehensive and well-rounded approach to collect data on general and functional requirements concerning safety and performance of Arthroscopy Systems.

6 Expected Deliverables:

Upon completion of the project, the following deliverables are expected:

6.1 A comprehensive report consisting outcomes of the study covering all aspects of the scope both shall be submitted in both paper and digital formats.

6.2 Along with the final report the survey formats and responses, questionnaires, results of testing, reports of visits, other relevant documents/ information to be appended.

7 BIS support or inputs to be provided to the Proposer:

BIS will provide access to latest available editions of Indian standards and/ or international standards relevant to the project, on request.

8 Delivery Milestones and Review Process:

8.1 The duration of the project shall be five months.

8.2 Interim report covering the review of the literature and existing stipulations thereof within **one month** from the date of award of project.

8.3 Report of site visits and product requirements identified during visits including manufacturing requirements, technologies used for production, quality control procedures employed and testing facilities **by the end of third month** from the date of award of project.

8.4 Final Report covering all the aspects of the TOR **by the end of fifth month**, from the date of award of project.

9 Nodal Point:

Member Secretary, MHD 02, may be contacted for more clarification on the R&D project (Email address: mhd2@bis.gov.in)