TERMS OF REFERENCE FOR THE R&D PROJECT

[Ophthalmic Instruments and Appliances Sectional Committee, MHD05 under Medical Equipment and Hospital Planning Department]

1.Title: Study and comparative analysis of functional and safety requirements of ocular prosthesis.

2.Background:

An ocular prosthesis, commonly known as an artificial eye, is a custom-made, removable device designed to replace a missing or non-functioning natural eye. It is meticulously crafted to resemble the natural appearance of the eye and is typically worn over a surgically implanted orbital implant or in a socket that has been surgically modified to accept the prosthesis. The primary objectives of an ocular prosthesis are to restore the aesthetic appearance of the eye and to promote the health and comfort of the eye socket. Different types of Ocular Prostheses are Scleral Shell Prosthesis, Orbital Prosthesis, Conformers, Cosmetic Shells, Implant-Retained Prosthesis (Consists of two parts: an orbital implant (placed within the eye socket) and a prosthetic eye.)

Each type of ocular prosthesis offers distinct advantages and is selected based on the individual's specific needs, anatomical considerations, and functional requirements. The fitting and customization of ocular prostheses are crucial to ensuring optimal comfort, appearance, and overall well-being for the wearer.

3. Objectives:

The objective is to collect and analyse data from both primary and secondary sources, and to have a report on ocular prosthesis that encompass materials, design, manufacturing processes, quality control, and performance characteristics, with the view of improving patient outcomes and ensuring product safety.

4. Scope:

4.1 Comprehensive study of existing literature of ocular prosthesis 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 industries, It is expected to carry out maximum of 10 visits, however, the final sample plan will be made after the data of manufacturing base and testing facilities available has been shared by the Proposer to the Nodal Officer of BIS.

a) Type of raw materials
b) Varieties manufactured
c) Manufacturing processes
d) In process quality controls
e) Manufacturing facilities (Automation, Industry 4.0)

f) Quality parameters
g) In-house test facilities
h) Parameters tested
i) Marking and labelling
j) Packaging
k) Finished materials quality parameters
l) Sampling plans
m) Sustainability practices [energy consumption, renewable energy sources, sustainable practices, 3Rs (Reuse, Reduce and Recycle), waste management and
n) disposal mechanisms, carbon footprints], future plans

4.6 Collection of user feedbacks

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 information in respect to the scope
c) Contact the relevant organizations and associations (Industry/ user associations) for gathering the data through structured questionnaires
d) Visits to the manufacturing units to observe and collect data as per the scope
e) Discussion with focused groups (Quality control personnel and person responsible for manufacturing) through structured questionnaires
f) Samples to be tested inhouse for functional 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. Expected Deliverables:

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

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. Delivery Milestones and Review Process:

a) The duration of the project shall be five months from the date of award of the project.
b) An interim report indicating the review of the literature, desktop research and sampling plan shall be submitted in one month from award of the project.
c) Draft report shall be submitted by the end of third month from award of the project.
d) Final report shall be submitted by the end of fifth month award of the project.

8. Support from BIS:

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

9. Nodal Point:

Member Secretary, MHD 05 may be contacted for more clarification on the R&D project (Email address: mhd5@bis.gov.in)