Declaration of Conformity

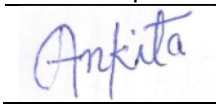
for the Ophthalmic Strips

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	Ophthalmic Strips
Legal Manufacturer: (Name on Label)	**Wizcure Medical Devices Pvt. Ltd.** G-1034, Phase – 3, RIICO Industrial Area Bhiwadi -301019, Rajasthan. INDIA.
Manufacturers SRN:	IN-MF-000036199
Basic UDI-DI:	890610345SHSTRIPZF
Variants:	As per Appendix II - Product Listing/Schedule
Intended Purpose:	The device is a graduated strip of filter paper used to evaluate the flow rate of tears produced by the eye. The extent to which the strip is wettened is an indicator of state of dryness of the eye. The strip may additionally have a band of blue dye. The blue dye spreads on the strip with the flow of the absorbed tears, providing an visual indication of the extent of wettening of the strip.
MDR Classification:	Class Is [Rule - 5]
Notified Body:	Intertek Medical Intertek Medical Notified Body, AB. Torshamnsgatan 43, Box 1103 SE – 164 22 Kista, SWEDEN Notified Body Number – 2862
EC Certificate:	28620173110
EU Authorised Representative:	Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 MALTA.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	In conformity with Article 19 after drawing up the technical documentations set out in Annexures Issuing of the Declaration of Conformity in accordance with Annexes II and III and **Chapters I and II of Annex IX.**

Name Ankita Gupta **Position** Management Representative

Signed  **Date** 09/04/2025 **Place** Bhiwadi, India

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008/Amd 1:2019	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity
EN ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by Particle concentration
ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
ISO 14644-4:2022	Cleanrooms and associated controlled environments — Part 4: Design, construction, and start-up
ISO 14644-5:2004	Cleanrooms and associated controlled environments -- Part 5: Operations

ISO 14644-9 : 2022	Cleanrooms and associated controlled environments -- Part 9: Classification of surface cleanliness by particle concentration
EN ISO 11135:2014	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 20416:2020	Medical Devices – Post Market Surveillance for Manufacturers
EN ISO 11737-1:2018	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	EMDN Code
SCH	Schirmer Tear Test Strip	M040302
TESTBL	Schirmer Tear Test Strip with Blue Band	M040302

Version History

Version	Compiled by	Date	Description
Issue 01 Rev 00	Komal Kumari	06/05/2018	DOC drawn as per requirement of ISO 13485:2016
Issue 02 Rev 00	Komal Kumari	24/04/2023	Fresh DOC drawn as per requirement of MDR 2017/745
Issue 02 Rev 01	Ankita Gupta	12/09/2024	Addition of Article 19 in conformity assessment route and place in DOC.
Issue 02 Rev 02	Ankita Gupta	09/04/2025	Revised the DOC, an audit finding during CE surveillance audit regarding the incorrect naming of notified body.