DECLARATION OF CONFORMITY

We, Stericon Pharma Pvt. Ltd, Plot No 9R, Sub Layout of Plot No.9, I phase, Bommasandra Industrial area, Bangalore – 560 099, Karnataka, India declare under our sole responsibility that the product:

BESTVIEW CALENDULA AUGEN TROPFEN- 5 ml, 10 ml, 15 ml
CE Certificate No.: 10075-2017-CE-IND-NA-PS Rev 14.0 Valid up to 27 May 2024

Class II b – As per rule 5 of MDD
to which this declaration relates is in conformity with the following Harmonised Standard(s) or other Normative document(s)

HARMONISED STANDARDS

Sl. No	Standard Number	Reference
1	EN ISO 13485:2016/A11:2021	Medical Devices –Quality management system requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices (ISO 14971:2019)
3	EN ISO 11737-1:2018/A1: 2021	Sterilization of health care products - Microbiological Methods - Part 1: Determination of a population of microorganisms on products. (ISO 11737-1:2018)
4	EN ISO 15223-1 :2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5	EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006 ,including Amd 1:2013)
6	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
7	EN ISO 10993 -12:2021	Biological evaluation of medical devices- Part – 12: Sample Preparation and reference materials (ISO 10993 -12:2021)
8	EN ISO 10993 -10:2023	Biological evaluation of medical devices — Part 10: Tests for skin sensitization (ISO 10993 -10:2021)

OTHER APPLICABLE STANDARDS

Sl. No	Standard Number	Reference
1.	ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971
2.	ISO 20417: 2021	Medical Devices – Information to be supplied by the manufacturer
3.	ISO 10993-1:2018	Biological evaluation of medical devices- Part – 1: Evaluation and testing within a risk management process
4.	ISO 10993 -5:2009	Biological evaluation of medical devices- Part – 5: Tests for in vitro Cytotoxicity
5.	ISO 10993 -11:2017	Biological evaluation of medical devices- Part – 11: Tests for Systemic Toxicity
6.	ISO 10993-17: 2002	Biological evaluation of medical devices- Part – 17: Establishment of allowable limits for leachable substances
7.	ISO 10993-18:2020/Amd 1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process — Amendment 1: Determination of the uncertainty factor

Stericon Pharma Pvt. Ltd. # 9R, Sub Layout of Plot No. 9, 1st Phase, Bommasandra Indl. Area, Bangalore - 560 099. INDIA
CIN : U33201KA1990PTC011056 Tel : +91 80 43571600 Email : info@stericon.net Website : www.stericon.net
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DECLARATION OF CONFORMITY

8.	ISO 17665-1:2006	Sterilisation of health care products- Moist heat - Part -1, Requirements for the development, validation and routine control of a sterilization process of medical devices
9.	ISO 13408-1:2008/A1:2013	Aseptic processing of health care products - Part 1: general requirements
10.	ISO 13408-2:2018	Aseptic processing of health care products - Part 2: Sterilizing Filtration
11.	ISO 13408-4:2005	Aseptic processing of health care products –Clean – in – place technologies
12.	ISO 13408-5:2006	Aseptic processing of health care products –Sterilisation in Place
13.	ISO 11137-2:2013/A1:2022	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
14.	IEC 62366-1:2015/A1:2020	Medical Devices –Application of Usability Engineering to Medical devices
15.	ISO 14730 :2014	Ophthalmic Optics-Contact lens care products- Antimicrobial preservative efficacy testing and guidance determining discard date
16.	ISO 14644 – 1:2015	Clean room and associated controlled environments
17.	ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
18.	EN 556-2:2015	Sterilization of medical devices - Requirements for medical devices to be designated STERILE - Part 2: Requirements for aseptically processed medical devices
19.	ISO/TR 20416:2020	Medical Devices- Post Market Surveillance for manufacturers
20.	ISTA 2 A:2011	Partial Simulation Performance Tests for packaged goods
21.	Drugs and cosmetic acts 1940 and rules there under.	Drugs and cosmetic acts
22.	ICH Q1A (R2)	Stability Testing of New Drug Substances and Products.
23.	MDD 93/42/EEC as amended by 2007/47/EC excluding section 4 of Annex II	Directive for medical device

and technical file STN /TF/STEP/R3 prepared as per Annex II excluding section 4 and maintained at Stericon Pharma Pvt. Ltd. Plot No: 9R, Sub Layout of Plot No 9, 1st Phase, Bommasandra Industrial Area, Bangalore - 560099, Karnataka, India, following the provisions of MDD 93/ 42 /EEC as amended by 2007/47/EC.
Finished medical devices are certified according to the MDD 93/42/EEC Annex II excluding section 4 by the Notified Body DNV Product Assurance AS, Veritasveien 1, N-1363 Hovik, Norway with ID no. 2460. to Stericon Pharma Pvt. Ltd. Plot No 9R, Sub Layout of Plot No.9, 1st phase, Bommasandra Industrial area, Bangalore – 560 099, Karnataka, India.

Our EC representative is MYM STC, SL.Avda.de los Rosales 32, 28935 Móstoles Madrid, Spain. Email: arturomolina@mym-stc.com, direccion@mym-stc.com
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Place: Bangalore

For Stericon Pharma Pvt Ltd

02/02/2024

Sr. Manager QC & MR

STERICON PHARMA PVT. LTD. Bangalore

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