HEALTHCARE
Medical Devices (Pvt) Ltd.
Wazirabad Road - 51050, Ugoki, Sialkot - Pakistan.

Ref: MD-DOC-01-005
Date: November 08, 2024

EU Declaration of Conformity

Medical Devices (Pvt) Ltd
Wazirabad Road, Ugoki
Sialkot. Pakistan.
Tel. +92 52 3571214 & 15
email: info@mdevices.com

Single Registration Number: **PK-MF-000021845**

DERMATOSCOPE

We hereby declare, under our sole responsibility, that the below mentioned devices conform to the General Safety and Performance Requirements (Annex I) in accordance with Medical Device Regulation (EU) 2017/745.

Intended Use:
Dermatoscope and associated accessories are used for the examination of Skin and disorders of the hair, scalp, and nails.

Article Description	Trade Name	Catalogue No.	Basic UDI-DI	GMDN/ EMDN
Dermatoscope Set, SIGMA 1000 Dermatoscope Head, SIGMA 1000	SIGMA 1000	808-550-25 808-550-01	896110278 DRMS808 QC	18021 / Z12040108
Dermatoscope Sets, SIGMA 2000, with Xenon & LED.	SIGMA 2000	818-011-25 818-012-35 818-013-35 818-014-35 818-016-25 818-017-35 818-018-35 818-019-35		
Dermatoscope Head, SIGMA 2000, with Xenon & LED. Dermatoscope Handle, SIGMA 2000.		818-001-25 818-003-35 818-005-25 818-007-35 805-001-25 805-002-35 805-004-35 805-049-35		
Dermatoscope Set, OMNI 3000, with Xenon & LED.	OMNI 3000	818-031-25 818-032-25 818-036-25 818-037-25		

Dermatoscope Head, OMNI 3000, with Xenon & LED.		818-021-25 818-023-25	896110278 DRMS808 QC	18021 / Z12040108
Dermatoscope Handle, OMNI 3000.	OMNI 3000	808-400-25 808-402-25		
Accessories for Dermatoscope			896110278 ACCES808 P4	
• Contact Plate with Scale • Contact Plate Plain	SIGMA 2000	818-901-01 818-903-01		
• Contact Plate with Scale • Contact Plate Plain	SIGMA 1000	808-550-06 808-550-07		
• Contact Plate with Scale • Contact Plate Plain	OMNI 3000	818-905-01 818-907-01		
Bulb for Dermatoscope LED for Dermatoscope	SIGMA 1000/2000, OMNI 3000	833-029-25 833-031-35 833-085-25 833-087-35	8964000576 LAMP833 MG	
Rechargeable Batteries	SIGMA 2000, OMNI 3000	808-067-35 808-062-35	-	

The Conformity Assessment Procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

It is further declared that the above Medical Devices are of Class I, by Rule 13 according to the Risk Classification of Annex VIII.

CE

Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO 15223-1:2021, ISO 10993-5: 2009, ISO 10993-10: 2010, IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + AMI:2012 (or IEC 60601-1:2012), IEC 60601-1-2:2014, IEC 60601-1-6 2010 + Amd1:2013, IEC 62366-1:2015.

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EU Authorized Representative:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Ph# 32.2.732.59.54
SRN:BE-AR-000000106

This Declaration of Conformity is valid until a revised Declaration of Conformity is issued.

SIALKOT- PAKISTAN	Qasim Raza, QA MANAGER	
Place (City & Country)	Position of Authorized Person	Signature

MEDICAL DEVICES (PVT) LIMITED SIALKOT PAKISTAN

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