



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

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/Reference No.	Basic UDI-DI	GMDN/EMDN
SIGMA 1000 Dermatoscope set with 2 Contact	SIGMA	808-550-25	896110278 DRMS808 QC	18021 / Z 120 401 08
Accessories for Sigma Dermatoscope <ul style="list-style-type: none">Contact Plate with ScaleContact Plate PlainDermatoscope Head		808-550-06 808-550-07 808-550-01		
OMNI 3000 Standard Dermatoscope Complete Set with LED		Omni		
OMNI 3000 Standard Dermatoscope Complete Set with Spare Lamp	808-560-25			
Accessories for Omni Dermatoscope <ul style="list-style-type: none">Dermatoscope HeadContact Plate with ScaleContact Plate Plain	808-560-01 808-560-06 808-560-07			
Bulb for Dermatoscope LED for Dermatoscope	SIGMA/ Omni	833-029-25 833-030-25		

It is further declared that the above Medical Devices are of Class I, by Rule 1 & 13 according to the Risk Classification of Annex VIII.





Ref: MD-DOC-00-005A
Date: April 17, 2023

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Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO 10993-5: 2009, ISO 10993-10:2010, ISO 15223-1:2021, ISO 780:2015, IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1 2:2014+AMD1:2020, IEC 62366-1:2015, IEC 60601-1-6, RoHS II Directive 2011/65/EU and RoHS III Directive 2015/863/EU.

EU Authorized Representative:

Obelis s.a.

Bd. Général Wahis 53

B-1030 Brussels, Belgium

Ph# 32.2.732.59.54

SRN:BE-AR-000000106

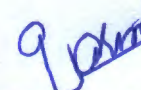

This Declaration of Conformity is valid until a revised Declaration of Conformity is issued.

SIALKOT- PAKISTAN

Place (City & Country)

Qasim Raza, QA MANAGER

Position of Authorized Person



Signature