



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

Ref: MD-QA-21-060
Date: June 22, 2021

EU Declaration of Conformity

Single Registration Number: Pending

We **Medical Devices (Pvt) Ltd**, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health products (Medical Devices) Regulations.

Manufacturing Site:

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

Contact Person:

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Article Description	Trade Name	Splenger Cat. No	MD Cat. No	GTIN/GMN	Intended Purpose
Clar Mirror MD-130 with Lightweight Metal Head Band, Dia 100mm , with LED illumination, and head band mounted battery box	Clar Headlight	570150	808-706-06	8964000965917	This is an instrument with a circular concave mirror attached to a head band used to project a beam of light when performing surgery or examination.
Omni 3000 SMARTLED 5500 Otoscope, Soft Green Pedia, In Case, with Spengler Branding.	Omni	570517	808-482-02	8964000965856	This is a device for examining ear canal and ear drum. It is primarily designed for examining the outer ear canal and tympanic membrane by means of light
Omni 3000 SMARTLED 5500 Otoscope, Blueberry, In Case, with Spengler Branding.	Omni	570517B	808-482-51	8964000965863	
Omni 3000 SMARTLED 5500 Otoscope, Coral Red, In Case, with Spengler Branding.	Omni	570517C	808-482-21	8964000965870	



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Omni 3000 SMARTLED 5500 Otoscope, Soft Green Pedia, In Case, with Spengler Branding.	Omni	570517P	808-482-41	8964000965887	
Omni 3000 Deluxe "Rechargeable" LED Otoscope Set "WOSB", In Hard Case, with Spengler Branding,	Omni	579530	808-482-03	8964000965894	
Zi-Mini Charging Station	Zi-mini	579534	808-052-00	8964000965979	This device designed to supply an electrical charge to rechargeable batteries, restoring the battery to an appropriate working condition.

It is certified that the above Medical Devices are of Class I according to Annex VIII and are in conformity with the (EU) MDR 2017/745, Annex IV.

CE MARK, Reg #: BE/CA01/1-15273-00003-CLI (For Otoscopes)
BE/CA01/1-15273-00003-CLI (For Clar Headlight)

Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO 15223-1:2016 (E), ISO 10993-5: 2009, ISO 10993-10: 2010, IEC 60601-1-2:2014

EU Representative: Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Ph# 32.2.732.59.54
CE Certificate # AP 9919-2020

SIALKOT- PAKISTAN
Place (City & Country)

QA MANAGER, Asif Sheraz
Position of Authorized Person



Signature