



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

Ref: MD-DOC-00-010A  
Date: April 15, 2023

## 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

### Headlights and Accessories

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:

Clar Mirrors and F/O Head lights both are intended to be used for illuminating the Body Surface for ENT and other examinations.

Article Description	Trade Name	Catalogue/Reference No.	Basic UDI-DI	GMDN/EMDN
Clar Mirror MD-110 with Ergonomic Head Band, 100mm Dia, with 6V Vacuum Bulb, and head band mounted battery box.	Clar Mirror MD-110	808-702-06	8964002408 COCM808 FH	34637/ L 031104
Clar Mirror MD-110 with Simple Head Band, 55mm Dia, with 6V Vacuum Bulb, and head band mounted battery box.		808-714-06		
Clar Mirror MD-130 with Ergonomic Head Band, Dia 100mm, with LED illumination, and Head Band Mounted Battery box.	Clar Mirror MD-130	808-706-30		
Clar Mirror MD-160 with Ergonomic Head Band, 100mm Dia, with 4/ 6/ 10V Vacuum Bulb, Switching Cable and Switching Direct mains transformer.	Clar Mirror MD-160	808-720-00		
Clar Mirror MD-160 with Ergonomic Head Band, 55mm Dia, with 4/ 6/ 10V Vacuum Bulb, Switching Cable and Switching Direct mains transformer.		808-722-00		
Clar Mirror MD-180 Model with Ergonomic Head Band, 55mm Dia, with 6v Vacuum Bulb, Switching Cable, Batter Box and Direct main transformer.	Clar Mirror MD-180	808-722-60		



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<b>Accessories for Clar Mirror:</b>				
Connecting Cable for CR-123 Battery Box. Length 30 cm.	-	808-090-00		
<b>Fiber Optic Headlights</b>				
F/O Headlight MD-750 with Black Head Band.	F.O Headlight MD-750	808-750-01	8964002408 HELT808 JQ	34637/V9099
F/O Micro Headlight MD-730 with Ergonomic Head Band.	F.O Headlight MD-730	808-746-01		
<b>Accessories for Fiber Optic Headlights</b>				
Light Concentrator for Head light.	F.O Headlight	808-750-11		

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.



**Applied Standards**

ISO 13485:2016, ISO 14971:2019, 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

*Qasim Raza*  
Signature

