



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

Ref: MD/QA/21-046, (Rev-01)
Date: August 03, 2021

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: Pending

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

| Article Description | Trade Name | Reference | BASIC UDI | GMDN |
|--|------------|-----------|-----------------------|-------|
| Otoscope F.O Complete, Blue Color, In Pouch, Polish | LS2 | 24850450 | 8964002407-OTFO808-QS | 12849 |
| Otoscope F.O Complete, Black Color, In Pouch, Polish | LS2 | 24850410 | | |
| Otoscope F.O Complete, Red Color, In Pouch, Polish | LS2 | 24850400 | | |
| Otoscope F.O Complete, Green Color, In Pouch, Polish | LS2 | 24850470 | | |

It is declared that the above Medical Devices are of Class I, Rule 5 according to the Risk Classification of Annex VIII.



Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO 15223-1:2016 (E), 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 # AF 4685 2016

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

SIALKOT- PAKISTAN
Place (City & Country)

Asif Sheraz, QA MANAGER
Position of Authorized Person


Signature

