



Medical Devices (Pvt) Ltd.

Wazirabad Road, Ugoki, Sialkot - Pakistan.

Ref: MD-DOC-00-007A

Date: April 17, 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**

GENERAL ENT DIAGNOSTIC 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:

The General ENT diagnostic accessories are intended to be used for different examinations related to throat, larynx, mouth, nose etc.

Article Description	Trade Name	Catalogue/Reference No.	Basic UDI-DI	GMDN/EMDN		
Metal Tongue Depressor	NOVA / PRIMA	808-280-01	896110278 DIAG808 DX	L1699 / L160299		
Adopter for Disposable Tongue Depressor		808-284-01				
Plain Mirror		808-270-20 808-272-22 808-270-02				
Curved illuminator		808-260-25 808-960-25				
Spreadable Nasal Speculum		808-250-01				
Tongue Depressor	VISIO 2000	808-518-01				
Plain Mirrors		808-516-01				
Illuminators (Straight / Curved)		808-508-25 808-510-35 808-512-25 808-514-35				
Nasal Illuminator complete with Nasal Speculum		808-500-25 808-502-35				



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Visio Tongue Blade Holder, Xenon	VISIO 1500	808-520-25 808-522-35	896110278 DIAG808 DX	L1699 / L160299
Killian Nasal Speculum with F/O Light Guide 75mm, Satin, S.S. 13 cm.	-	830-132-75		
Nasal Illuminator complete with Nasal Speculum	OMNI 3000	808-416-25 808-466-01 808-466-02		
Pocket Light, Ear Light Probe		808-464-01 808-414-25 808-294-10 808-294-01		
Insufflation Adaptor	-	808-298-01		
Insufflation Bulb	-	808-296-01		
Replacement Bulb	NOVA/ PRIMA/ VISIO / OMNI	833-033-25 833-070-35 833-009-25 833-013-25 833-015-35 833-021-25 833-023-35		

It is further declared that the above Medical Devices are of Class I, by Rule 5 & 13 according to the Risk Classification of Annex VIII.



Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, 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.
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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

