



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

Ref: MD-DOC-00-009A
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**

Wall Diagnostic Stations

We hereby declare, under 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 Wall Diagnostic Stations "VISIO 5Plus HQ Power Transformer" serves as a constant power source for 3.5V VISIO 5 instrument heads eliminating the need for conventional and rechargeable batteries. The handles in the units are equipped with brightness control mechanism to achieve the required light for each examination.

Article Description	Trade Name	Catalogue/Reference No.	Basic UDI-DI	GMDN/EMDN
Wall Diagnostic Station, VISIO 5GE HQ Basic 3.5V Xenon	VISIO 5 PLUS HQ	805-900-01	896110278 WDIS808 TD	16933/V9099
Wall Diagnostic Station, VISIO 5GE HQ Basic 3.5V LED		805-902-01		
Wall Diagnostic Station, VISIO 5SE HQ Basic 3.5V Xenon		805-900-26		
Wall Diagnostic Station, VISIO 5SE HQ Basic 3.5V LED		805-902-26		
Wall Diagnostic Station, VISIO 5XE HQ Basic 3.5V Xenon		805-900-46		
Wall Diagnostic Station, VISIO 5XE HQ Basic 3.5V LED		805-902-46		
Wall Diagnostic Station, VISIO 5XE "V-Max" Basic 3.5V Xenon		805-930-01		
Wall Diagnostic Station, VISIO 5XE "V-Max" Basic 3.5V LED		805-932-01		
Wall Diagnostic Station, VISIO 5GE HQ Premier 3.5V Xenon		805-904-01		
Wall Diagnostic Station, VISIO 5GE HQ Premier 3.5V LED		805-906-01		
Wall Diagnostic Station, VISIO 5SE HQ Premier 3.5V Xenon		805-904-26		
Wall Diagnostic Station, VISIO 5SE HQ Premier 3.5V LED		805-906-26		



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Wall Diagnostic Station, VISIO 5XE HQ Complete 3.5V Xenon	VISIO 5 PLUS HQ	805-908-01	896110278 WDIS808 TD	16933/ V9099
Wall Diagnostic Station, VISIO 5XE HQ Complete 3.5V LED		805-910-01		
Wall Diagnostic Station, VISIO 5XE HQ Ophthalmic 3.5V Xenon		805-912-01		
Wall Diagnostic Station, VISIO 5XE HQ Ophthalmic 3.5V LED		805-914-01		

It is further declared that the above Medical Devices are of Class I, by Rule 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


Signature