体系中心 2024-05-08 受控文件

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Name: Xiamen Winner Medical Co., Ltd. Address: Area A, 6F, No. 588-1, TongFu Road, 361100 TongAn District, Xiamen City, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000018733
European Representative:	Name: MedPath GmbH Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN:	DE-AR-000000087
Product Name:	Nose Clip
Trade Name:	N.A.
Product Type:	TW8501,TW8504
Basic UDI-DI:	697038572NC2K
EMDN Code:	R03010280
Classification Acc. to MDR Ax. VIII:	Class I, Rule 1
Applied Common Specification/ Standard:	EN ISO 13485:2016/A11:2021 · EN ISO 14971:2019/A11:2021 · EN ISO 10993-1:2020 EN ISO 10993-5:2009 · EN ISO 10993-10:2023 · EN ISO 15223-1:2021 EN ISO 10993-23:2021 · EN ISO 20417: 2021 · EN 62366-1: 2015+A1:2020
Conformity Assessment Procedure:	MDR Annex II + Annex III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Place of Issue:	Xiamen, China
Date of Issue:	2024.05.08
Signature:	
Name:	Mr. Qing, Wu
Position:	PRRC / Management Representative