



DECLARATION OF CONFORMITY

We

Xmetix Ltd,
13 Wadi Al Hajj Street,
Nazareth, 1603615
Actor ID/SRN: IL-MF-000047424

Declare and under own sole responsibility that the medical device:

TAK710

Automated Tourniquet

meets applicable provisions of the Medical Device Regulation (EU) 2017/745. All relevant documents are retained at the premises of the manufacturer.

Intended Purpose: The TAK710 is an automated tourniquet intended to be used in cases of bleeding from an open wound of an arm or a leg. It is used to prevent life-threatening blood loss.

Risk Class per Annex VIII Class I (non-sterile) as per rule 1.

Conformity assessment Annex II and III Technical Documentation for Class I EU Medical Devices and issues a declaration of conformity (self-certification)

Representative in EU MedNet EC-REP GmbH. SNR: DE-AR-000000002
Borkstraße 10, 48163 Münster, Germany

GMDN Code: 35925 (Arm/Leg tourniquet, single use)

EMDN Code: V9003 (Tourniquets)

Place Xmetix Ltd
Date November 16, 2024
Name Igor Naroditsky
Title Regulatory Affairs

Signature

LIST OF APPLIED STANDARDS AND COMMON SPECIFICATIONS

Standards and CS	Description
ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Information supplied by the manufacturer with medical devices
EN 15223-1:2021	Symbols to be used with medical device labels, labeling and information to be supplied
IEC 62366-1:2015/AMD 1:2020	Medical devices - Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-7:2008+Cor 1:2009+Amd1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60529:1989/AMD2:2013/COR1:2019	Degrees of protection provided by enclosures (IP Code)
MIL STD 810G	Test Method Standard, Environmental Engineering Considerations and Laboratory Tests

Model reference

Product	Basic UDI-DI
TAK710 automated tourniquet - A tourniquet intended to be used in cases of bleeding from an open wound of an arm or a leg.	729002008700TAK710PP