

# EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of wrapyX GmbH who declares that the devices mentioned within this document are in conformity with the EU Medical Device Regulation 2017/745 (MDR) and its corrigenda.

## Manufacturer Details

Name	wrapyX GmbH
Address	Ziegelhausmatte 3, 6142 Gettnau, Switzerland.
CHRN	CHRN-MF-20010371
SRN	CH-MF-000048535

## EU Authorised Representative Details

Name	Specculo Limited
Address	10/1 Sir M.A. Refalo Avenue, Balzan BZN1600, Malta
SRN	MT-AR-000034988

## Device Details

Basic UDI-DI	7649989007BNDG_ClassicE4
Product Name	wrapyX
Variants	wrapyPatch, wrapyRound
Intended Purpose	It is used for protecting the puncture site to stop bleeding after injection, and in the meantime, it can provide protection against infection.
Risk Classification	In accordance with Annex VIII of the EU MDR, this product is classified as a Class 1 device through Rule 4.
Conformity Assessment Procedure	Issuing the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation as laid out in Annexes II and III of the EU MDR.

**Signature**  \_\_\_\_\_

**Date** 28 Jul 2025 \_\_\_\_\_

**Name** Rijad Leka \_\_\_\_\_

**Place** Gettnau, Switzerland \_\_\_\_\_

**Function** Founder & Developer \_\_\_\_\_

**OBO** wrapyX \_\_\_\_\_

## Appendix A

### Standards.

Manufacturer Name declares conformity with the following Common Specifications and Harmonised Standards.

Title/Reference	Description
EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes

The following Harmonised Standards and guidance have been taken into consideration.

Title/Reference	Description
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
EN ISO 14698-1:2004	Cleanrooms and associated controlled environments — Biocontamination control Part 1: General principles and methods.
ISO 14698-2:2003	Cleanrooms and associated controlled environments — Biocontamination control Part 2: Evaluation and interpretation of biocontamination data.
EVS-EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
MEDDEV 2.7/1 rev. 4	Guidance on clinical evaluation
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-13	Clinical evaluation assessment report template
MDCG 2019-9 rev.1	Summary of safety and clinical performance

### Variants

The below table indicates all the product and variants which are covered by this Declaration of Conformity.

UDI-DI	Name	EMDN
76499890070003	wrapyRound	M040201
76499890071000	wrapyPatch	M040201

### Document History

Revision	Date	Author	Description
00	11 Jul 2025	Kenneth Shaw	First issue.