EU MDR (2017/745)

DECLARATION OF CONFORMITY

SafeR Syringe

Manufacturer: Roncadelle Operations srl

Via Renolda 10 - 25030 Castel Mella (BS)-Italy

Phone: + 39 030 67 24 300

https://www.safersyringe.com/

SRN IT-MF-000017979

We, (legal manufacturer), hereby declare under our sole responsibility that the product(s) specified herein conform(s) to EU Medical Device Regulation 2017/745.

Conformity assessment procedure: according to the Annex IX of Regulation MDR 2017/745

Conformity Assessment Certificate(s): ITH 2409169 1

Certificate Expiry date: 25/07/2027

Notified Body: TÜV RHEINLAND ITALIA SRL

Notified Body Code: 1936

PRODUCT(S) IN SCOPE:

Product name:	Safer Syringe
Product description:	Safety syringe
Product codes:	Refer to Annex I
Basic UDI-DI:	805699902SyringeCP00201F9
Classification rule:	Rule 2
Risk Class:	Class I sterile
Intended purpose:	Safer Syringe is intended to provide a safe, accurate and reliable method for the aspiration of fluids or for the

injection of fluids immediately after filling preventing possible infections due to needle stick injuries and syringe reuse.

Applied Standards/Common Specifications: Refer to Annex II

SIGNATURE *(on behalf of manufacturer)*:

Massimo Rossi

Quality & Regulatory Manager

DATE : 09 March 2023

PLACE: Castel Mella

Revision history

Rev.	Date	Description
1	03 Aug 2022	First Emission
2	02 Dec 2022	Standard List Updated
3	09 Mar 2023	Typo correction

Document Owner	Marta Gasparini
DCR#	DCR/22-81

Annex I

Product Name	Size	Product Codes	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g., GMDN)
SafeR Syringe	1ML	SFS0100	805699902SyringeCP00201F9	GMDN 35904
SafeR Syringe	2ML	SFS0200		GMDN 35904
SafeR Syringe	2,25ML	SFS0225		GMDN 35904
SafeR Syringe	3ML	SFS0300		GMDN 35904
SafeR Syringe	5ML	SFS0500		GMDN 35904

Annex II

Applied Standards/Common Specification(s)

The following standards/common specifications were used to demonstrate conformity:

Number	Title
UNI CEI EN ISO 13485 (EN ISO 13485)	Medical devices - Quality management systems - Requirements for regulatory purposes
UNI CEI EN ISO 14971 (EN ISO 14971)	Medical devices - Application of risk management to medical devices
CEI EN 62366-1 (EN 62366-1)	Medical devices Application of usability engineering to medical devices
UNI EN ISO 7886-1 (EN ISO 7886-1)	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
UNI EN ISO 7886-4 (EN ISO 7886-4)	Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature
UNI EN ISO 23908 (EN ISO 23908)	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
UNI CEI EN ISO 15223-1 (EN ISO 15223-1)	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
UNI EN ISO 10993-1 (EN ISO 10993-1)	Biological evaluation of medical devices - Evaluation and testing within a risk management process
UNI EN ISO 10993-7 (EN ISO 10993-7)	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
UNI EN 556-1 (EN 556-1)	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
UNI CEI EN ISO 20417 (EN ISO 20417)	Medical devices - Information to be supplied by the manufacturer

Number	Title
UNI EN ISO 11607-1 (EN ISO 11607-1)	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
UNI EN ISO 11607-2 (EN ISO 11607-2)	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
UNI EN ISO 11135 (EN ISO 11135)	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
UNI EN ISO 11737-1 (EN ISO 11737-1)	Sterilization of health-care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
UNI EN ISO 11737-2 (EN ISO 11737-2)	Sterilization of health-care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN CEI ISO 80369-7 (EN ISO 80369-7)	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
EN ISO 80369-20 (EN ISO 80369-20)	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods