Roncadelle Operations

EU MDR (2017/745)

DECLARATION OF CONFORMITY

SafeR Sting

Manufacturer: Roncadelle Operations srl

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Phone: + 39 030 67 24 300

https://www.safersyringe.com/

SRN IT-MF-000017979

We, Roncadelle Operations srl, 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 Sting
Product description:	Retractable needle
Product codes:	Refer to Annex I
Basic UDI-DI:	805699902StingCP002000177
Classification rule:	Rule 6
Risk Class:	Class IIa
Intended purpose:	Safer Sting is intended to provide a safe, accurate and reliable method for the aspiration of fluids or for the injection of fluids immediately after

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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 : 04 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

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Annex I

Product Name	Size	Product Codes	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g., GMDN)
SafeR Sting	18G x 32mm	SFB1832	805699902StingCP002000177	GMDN 59230
SafeR Sting	20G x 38mm	SFN2038	805699902StingCP002000177	GMDN 59230
SafeR Sting	20G x 32mm	SFN2032	805699902StingCP002000177	GMDN 59230
SafeR Sting	20G x 25mm	SFN2025	805699902StingCP002000177	GMDN 59230
SafeR Sting	21G x 38mm	SFN2138	805699902StingCP002000177	GMDN 59230
SafeR Sting	21G x 32mm	SFN2132	805699902StingCP002000177	GMDN 59230
SafeR Sting	21G x 25mm	SFN2125	805699902StingCP002000177	GMDN 59230
SafeR Sting	22G x 38mm	SFN2238	805699902StingCP002000177	GMDN 59230
SafeR Sting	22G x 32mm	SFN2232	805699902StingCP002000177	GMDN 59230
SafeR Sting	22G x 25mm	SFN2225	805699902StingCP002000177	GMDN 59230
SafeR Sting	23G x 38mm	SFN2338	805699902StingCP002000177	GMDN 59230
SafeR Sting	23G x 32mm	SFN2332	805699902StingCP002000177	GMDN 59230
SafeR Sting	23G x 25mm	SFN2325	805699902StingCP002000177	GMDN 59230
SafeR Sting	25G x 25mm	SFN2525	805699902StingCP002000177	GMDN 59230
SafeR Sting	25G x 16mm	SFN2516	805699902StingCP002000177	GMDN 59230
SafeR Sting	26G x 25mm	SFN2625	805699902StingCP002000177	GMDN 59230
SafeR Sting	26G x 16mm	SFN2616	805699902StingCP002000177	GMDN 59230
SafeR Sting	27G x 13mm	SFN2713	805699902StingCP002000177	GMDN 59230

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Annex II

Applied Standards/Common Specification(s)

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

Number	Title 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 7864 (EN ISO 7864)	Sterile hypodermic needles for single use - Requirements and test methods
UNI EN ISO 6009 (EN ISO 6009)	Hypodermic needles for single use — Colour coding for identification
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

Number	Title Title
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
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 9626 (EN ISO 9626)	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
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