EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

I'M MEDICARE SARL

PARC INDUSTRIEL SIDI BOU OTHMANE, LOT 21 COMMUNE SIDI BOU OTHMANE, BENGUERIR, MARRAKECH 43303, MOROCCO

Manufacturer SRN: MA-MF-000037665

Authorised Representative:

EUCEREP B.V. ROALD DAHLLAAN 33, 5629MC, EINDHOVEN, NETHERLANDS

Scope:
Devices channelling substances

Certificate Number:
28620234405

Revision:
00

Initial Certification Date:
27 January 2026

Certificate Decision Date:
27 January 2026

Certificate Issue Date:
27 January 2026

Certificate Expiry Date:
19 January 2031

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 ACTY-2024-282176**
	Stage 2 ACTY-2024-282177
TD Assessment reference	**TD00643-001 AD SYRINGE**
Change notice reference	**CN00643-003**
	CN00643-005

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620234405	27 January 2026	Initial certificate

Certificate Number:
28620234405

Revision:
00

Initial Certification Date:
27 January 2026

Certificate Decision Date:
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PRODUCT LIST FOR CERTIFICATE

Issued to: I'M MEDICARE SARL

Certificate number: 28620234405

Certificate valid from: 2026-01-27

Product list issue date:
27 January 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Devices channeling substances			
Basic UDI-DI: 611800222ADRUPVZ			
IT-02-12-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-12-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-13-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-13-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-14-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-14-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-18-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-18-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-19-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-19-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-20-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-20-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-21-LL - RUP SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-02-21-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-22-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-22-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-23-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-23-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-24-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-24-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-25-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-25-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-26-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-02-26-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-12-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-12-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-13-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-13-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-14-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-14-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-18-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-18-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-19-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-19-LS - RUP SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-04-20-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-20-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-21-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-21-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-22-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-22-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-23-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-23-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-24-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-24-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-25-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-25-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-26-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-04-26-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-12-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-12-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-13-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-13-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-14-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-14-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-18-LL - RUP SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-06-18-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-19-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-19-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-20-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-20-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-21-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-21-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-22-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-22-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-23-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-23-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-24-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-24-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-25-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-25-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-26-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-06-26-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-12-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-12-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-13-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-13-LS - RUP SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-08-14-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-14-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-18-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-18-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-19-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-19-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-20-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-20-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-21-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-21-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-22-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-22-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-23-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-08-26-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-24-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-24-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-25-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-25-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-26-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-26-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-27-LL - RUP SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-16-27-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-28-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-28-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-29-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-29-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-30-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-30-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-31-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-31-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-32-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-32-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-34-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-34-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-35-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-35-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-36-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-36-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-40-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-40-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-41-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-41-LS - RUP SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-16-42-LL - RUP SYRINGES	Class IIa A020199		2026-01-27
IT-16-42-LS - RUP SYRINGES	Class IIa A020199		2026-01-27
Basic UDI-DI: 611800222ADSFXV9			
IT-01-24-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-01-27-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-01-30-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-18-24-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-18-27-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-18-30-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-19-24-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-19-27-FX - AD SYRINGE	Class IIa A020199		2026-01-27
IT-19-30-FX - AD SYRINGE	Class IIa A020199		2026-01-27
Basic UDI-DI: 611800222HYPONDLEL			
IT-00-01-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-01-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-02-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-02-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-03-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-03-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-04-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-04-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-00-05-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-05-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-06-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-06-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-07-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-07-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-08-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-08-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-09-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-09-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-10-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-10-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-11-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-11-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-12-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-12-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-13-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-13-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-14-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-14-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-15-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-00-15-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-16-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-16-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-17-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-17-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-18-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-18-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-19-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-19-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-20-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-20-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-21-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-21-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-22-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-22-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-23-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-23-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-24-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-24-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-25-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-25-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-00-26-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-26-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-27-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-27-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-28-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-28-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-29-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-29-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-30-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-30-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-31-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-31-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-32-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-32-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-33-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-33-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-34-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-34-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-35-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-35-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-36-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-00-36-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-37-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-37-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-38-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-38-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-39-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-39-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-40-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-40-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-41-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-41-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-42-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-42-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-43-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-43-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-44-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-44-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-45-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-45-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-46-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-46-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-00-47-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-47-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-48-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-48-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-49-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-49-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-50-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-50-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-51-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-51-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-52-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-52-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-53-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-53-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-54-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-54-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-55-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-55-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
IT-00-56-BN - Hypodermic Needle	Class IIa A0101010102		2026-01-27
IT-00-56-SN - STERILE HYPODERMIC NEEDLE	Class IIa A0101010102		2026-01-27
Basic UDI-DI: 611800222HYPOSRGGD			

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-03-12-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-12-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-13-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-13-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-14-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-14-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-18-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-18-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-19-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-19-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-20-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-20-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-21-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-21-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-22-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-22-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-23-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-23-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-24-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-24-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-25-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-03-25-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-26-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-03-26-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-12-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-12-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-13-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-13-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-14-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-14-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-18-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-18-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-19-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-19-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-20-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-20-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-21-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-21-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-22-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-22-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-23-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-23-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-05-24-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-24-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-25-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-25-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-26-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-05-26-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-12-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-12-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-13-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-13-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-14-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-14-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-18-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-18-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-19-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-19-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-20-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-20-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-21-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-21-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-22-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-07-22-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-23-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-23-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-24-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-24-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-25-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-25-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-26-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-07-26-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-12-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-12-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-13-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-13-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-14-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-14-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-18-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-18-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-19-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-19-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-20-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-20-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-09-21-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-21-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-22-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-22-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-23-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-09-23-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-12-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-13-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-14-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-18-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-19-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-20-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-21-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-22-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-10-23-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-24-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-24-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-25-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-25-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-26-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-26-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-17-27-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-27-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-28-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-28-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-29-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-29-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-30-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-30-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-31-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-31-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-32-LL - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
IT-17-32-LS - HYPODERMIC SYRINGES	Class IIa A020199		2026-01-27
Basic UDI-DI: 611800222SYRINSBL			
IT-12-36-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-12-37-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-12-38-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-12-39-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-13-35-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-13-36-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-13-37-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-13-38-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-13-39-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-14-36-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-14-37-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-14-38-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-14-39-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-15-35-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-15-36-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-15-37-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-15-38-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-15-39-00 - STERILE INSULIN SYRINGE	Class IIa A02010601		2026-01-27
IT-20-43-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-44-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-45-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-46-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-47-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-48-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-49-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-50-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-51-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-52-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-53-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
IT-20-54-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-55-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27
IT-20-56-00 - Insulin Pen Needle	Class IIa A0101010202		2026-01-27

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.