

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, restricted to the aspects relating to the conformity of the devices with sterility and metrological requirements, 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:

Sterility and metrology aspects of Class Is and Class Im devices as detailed in attached product list

Certificate Number:
28620233274

Revision:
00

Initial Certification Date:
20 January 2026

Certificate Decision Date:
20 January 2026

Certificate Issue Date:
20 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.



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
Change notice reference	CN00643-003
	CN00643-005

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

Certificate Number:
28620233274

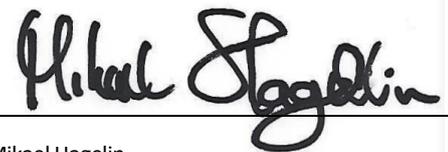
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CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620233274	20 January 2026	Initial certificate

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PRODUCT LIST FOR CERTIFICATE

Issued to: I'M MEDICARE SARL

Certificate number: 28620233274

Certificate valid from: 2026-01-20

Product list issue date:
20 January 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Class I devices with a measuring function			
Basic UDI-DI: 611800222SRGBLK4Z			
IT-02-00-BS - 3ML BULK AD SYRINGE	Class I(m) A020199		2026-01-20
IT-03-00-BS - 3ML BULK HYPODERMIC SYRINGE	Class I(m) A020199		2026-01-20
IT-04-00-BS - 5ML BULK AD SYRINGE	Class I(m) A020199		2026-01-20
IT-05-00-BS - 5ML BULK HYPODERMIC SYRINGE	Class I(m) A020199		2026-01-20
IT-06-00-BS - 10ML BULK AD SYRINGE	Class I(m) A020199		2026-01-20
IT-07-00-BS - 10ML BULK HYPODERMIC SYRINGE	Class I(m) A020199		2026-01-20
IT-08-00-BS - 20ML BULK AD SYRINGE	Class I(m) A020199		2026-01-20
IT-09-00-BS - 20ML BULK HYPODERMIC SYRINGE	Class I(m) A020199		2026-01-20
IT-10-00-BS - 50/60 ML BULK SYRINGE	Class I(m) A020199		2026-01-20
IT-11-00-BS - 50/60 ML BULK SYRINGE CATHETER TIP	Class I(m) A020199		2026-01-20
IT-17-00-BS - 1ml BULK HYPODERMIC SYRINGE	Class I(m) A020199		2026-01-20
Class I sterile devices with a measuring function			
Basic UDI-DI: 611800222ADRUPWO6M			
IT-02-00-LL - RUP SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20

¹The 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-04-00-LL - RUP SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20
IT-06-00-LL - RUP SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20
IT-08-00-LL - RUP SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20
Basic UDI-DI: 611800222HYPOSRGGD			
IT-11-00-CT - HYPODERMIC SYRINGES	Class I(s,m) A02010203		2026-01-20
Basic UDI-DI: 611800222HYPSYRWO2A			
IT-03-00-LL - HYPODERMIC SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20
IT-05-00-LL - HYPODERMIC SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20
IT-07-00-LL - HYPODERMIC SYRINGES WITHOUT NEEDLE	Class I(s,m) A020199		2026-01-20
IT-09-00-LL - HYPODERMIC SYRINGES WITHOUT NEEDLE	Class I(s,m) A020102010202		2026-01-20



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