EC CERTIFICATION

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.

Medical Devices, Inc.

11501 Metro Airport Center Drive, Suite 100, Romulus, Michigan, 48174, United States

Manufacturer SRN: US-MF-000033022

Authorised Representative Name:

Obelis s.a.

Boulevard Général Wahis, 53 1030 Brussels, Belgium

Scope:

Wound Dressings

Certificate Number:
28620178174

Revision:
00

Initial Certification Date:
14 June 2024

Certificate Decision Date:
14 June 2024

Certificate Issue Date:
14 June 2024

Certificate Expiry Date:
05 June 2029

Brian Mather
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

Technical Assessment Report Reference	**TD000187-01 Medical Devices, Inc Halo Vent Single Pack IFAK Pack**
Audit Report Reference	**Stage 1 audit ACTY-2022-525660**
	Stage 2 audit ACTY-2022-525661
	Stage 2 (repeat) ACTY-2022-525646
	Special Surveillance ACTY-2024-199535

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620178174

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PRODUCT LIST FOR CERTIFICATE

Issued to: Medical Devices Inc.

Certificate number: 28620178174

Certificate valid from: 2024-06-14

Product List Issue Date:
14 June 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Wound Dressings			
Basic UDI-DI: 08500106081216-10000NW			
1216-10008 - Halo Vent Single Pack IFAK Pack	Class IIb M040403	A non-sterile hydro-colloid dressing that is used to cover and protect chest wounds allowing venting to relieve pressure to prevent tension pneumothorax.	2024-06-14
1216-10020 - Halo Vent 2 Pack IFAK Pack	Class IIb M040403	A non-sterile hydro-colloid dressing that is used to cover and protect chest wounds allowing venting to relieve pressure to prevent tension pneumothorax.	2024-06-14

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