

# 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  
- hydrogel dressing

**Certificate Number:**

28620178174

**Revision:**

01

**Initial Certification Date:**

14 June 2024

**Certificate Decision Date:**

17 October 2024

**Certificate Issue Date:**

17 October 2024

**Certificate Expiry Date:**

05 June 2029



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

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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.

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**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
Change Notes	CN00187-005

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620178174-00	14 June 2024	Initial Issue
28620178174-01	17 October 2024	Change to scope and product list

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28620178174

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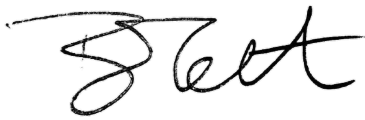


## PRODUCT LIST FOR CERTIFICATE

**Issued to:** Medical Devices Inc.  
**Certificate number:** 28620178174-01  
**Certificate valid from:** 2024-10-17

**Product List Issue Date:**  
17 October 2024

Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
<b>Wound Dressings</b>			
<i>Basic UDI-DI: 08500106081216-10000NW</i>			
1216-10008 - Halo Vent Single Pack IFAK Pack	Class IIb M040405	A non-sterile hydrogel 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 M040405	A non-sterile hydrogel 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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<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

