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.

Hangzhou Zeo-Innov Life Technology Co., Ltd

Room 101 and 301-8, Building 2, No.291 Fucheng road, Xiasha street, Qiantang New district, Hangzhou city, Zhejiang province, P. R. China 330114
Manufacturer SRN: CN-MF-000026229

Authorised Representative:
Wellkang Ltd
Enterprise Hub, NW Business Complex,, 1 Beraghmore Rd, BT48 8SE, Derry, Northern Ireland

Scope:
Wound dressings

Certificate Number:
28620252097

Revision:
00

Initial Certification Date:
24 July 2026

Certificate Decision Date:
24 July 2026

Certificate Issue Date:
24 July 2026

Certificate Expiry Date:
23 July 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	**ACTY-2026-444270**
	ACTY-2026-469425
Last Technical Documentation reference	**TD00348-001**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620252097	24 July 2026	Initial certificate

Certificate Number:
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PRODUCT LIST FOR CERTIFICATE

Issued to: Hangzhou Zeo-Innov Life Technology Co., Ltd

Certificate number: 28620252097

Certificate valid from: 2026-07-24

Product list issue date:
24 July 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Wound dressings			
Basic UDI-DI: 697206031ZHG001D8			
P (Sheet) - Zeolite Hemostatic Gauze folded width × folded length, Layers (1-9)cm ×(1- 10)cm, 1-12 Layers	Class IIb M02030201	Medical device is indicated for emergency use to control moderate to severe bleeding	2025-09-03
Z (Folded) - Zeolite Hemostatic Gauze width × folded width, Layers (1-10)cm ×(1- 9)cm, 1-12 Layers	Class IIb M02030201	Medical device is indicated for emergency use to control moderate to severe bleeding	2025-09-03

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