EU Declaration Of Conformity

Manufacturer:

Mondomed NV
Middenweg 20
3930 Hamont-Achel
Belgium

Single Registration Number (SRN): BE-MF-000001283

Basic UDI-DI: 542502543wounddressing6V

Products:

Catalogue (REF) Number	Device	Scope certificate
409 760/1	Vivano®Med White Foam Small (7.5 x 10 x 0.9 cm)	Sterile wound dressings intended to assist in wound healing by managing exudate in wounds and by maintaining a moist wound environment (class IIb sterile)
409 761/1	Vivano®Med White Foam Large (15 x 10 x 0.9 cm)	

EMDN code: M040499

Intended purpose/use: Mondomed wound dressings are sterile, single use, wet, hydrophilic wound dressings, made out of polyvinyl alcohol (PVA) foam with good absorbent properties, for negative pressure wound therapy.

Classification MDR 2017/745 Class IIb sterile (Rule 4)

Mondomed NV herewith declares under its sole responsibility that the above mentioned products meet the requirements of:

- EN ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes
- Medical Device Regulation 2017/745

and that all documentation to support this Declaration of Conformity is available for review and shall be kept on file at Mondomed NV.

Notified Body:

SGS Belgium NV
Identification number 1639

Conformity Assessment route: MDR, Annex IX – Conformity assessment based on Quality Management System and on assessment of Technical Documentation.

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ISO certificate Number: BE22/00000140

MDR CE certificate number: BE24/00000069

Date MDR CE Marking affixed: 2026

Signed:

Pasquale Cimmino,
CEO

Place and Date: Hamont-Achel, 12 JUN 2026

Used Common Specification:

No common specification is available for the devices

Used harmonized standards:

EN ISO 13485:2016/AC:2018/A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
ISO 10993-17:2023	Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents
ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
EN ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation
EN ISO 11137-1:2015/A2:2019	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

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EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products – Microbiological methods – Part 2: Test for sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices

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