

## Declaration Of Conformity

**Manufacturer:** Mondomed NV  
Middenweg 20  
3930 Hamont-Achel  
Belgium

**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 with high absorption capacity, made of polyvinyl alcohol, for negative pressure wound treatment (class IIb sterile) |
| 409 761/1              | Vivano®Med White Foam Large (15 x 10 x 0.9 cm)  |                                                                                                                                             |

**GMDN code:** 47406

**Classification MDD 93/42/EEC** Class IIb (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
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

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

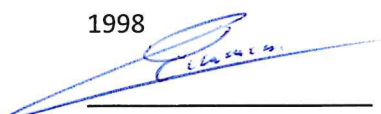
**Conformity Assessment route:** MDD, Annex II – Full Quality Assurance System excluding section 4.

**ISO certificate Number:** BE22/00000140

**CE certificate number:** BE09/951042

**Date CE Marking affixed:** 1998

**Signed:**



Pasquale Cimmino,  
CEO

**Date:** 09JAN2022

**Used harmonized standards:**

|                             |                                                                                                                                                                         |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN ISO 13485:2016/AC:2018   | Medical devices — Quality management systems — Requirements for regulatory purposes                                                                                     |
| EN ISO 14971:2012           | Medical devices — Application of risk management to medical devices                                                                                                     |
| EN ISO 15223-1:2016         | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements                                |
| EN 1041:2008                | Information supplied by the manufacturer of medical devices                                                                                                             |
| EN ISO 10993-1:2009/AC:2010 | Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process                                                              |
| EN ISO 10993-3:2014         | Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity                                                    |
| EN ISO 10993-5:2009         | Biological evaluation of medical devices — Part 5: tests for in vitro cytotoxicity                                                                                      |
| EN ISO 10993-6:2009         | Biological evaluation of medical devices – Part 6: Tests for local effects after implantation                                                                           |
| EN ISO 10993-11:2009        | Biological evaluation of medical devices — Part 11: Tests for systematic toxicity                                                                                       |
| EN ISO 10993-12:2012        | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials                                                                          |
| EN ISO 10993-17:2009        | Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances                                                          |
| EN ISO 10993-18:2009        | Biological evaluation of medical devices - Part 18: Chemical characterization of materials                                                                              |
| 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         | Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose                                                                         |

|                             |                                                                                                                                                                            |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN ISO 11607-1:2009         | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems                                    |
| EN ISO 11607-2:2006         | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes                                          |
| EN ISO 11737-1:2006/AC:2009 | Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products                                           |
| EN ISO 11737-2:2009         | Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process |
| EN 556-1:2001/AC:2006       | Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices            |

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| 1255891                | Coldex® Extra<br>(7.5 x 10 x 0.9 cm) | Sterile wound dressings with high absorption capacity, made of polyvinyl alcohol, for negative pressure wound treatment (class IIb sterile) |
| 1255892                | Coldex® Extra<br>(15 x 10 x 0.9 cm)  |                                                                                                                                             |

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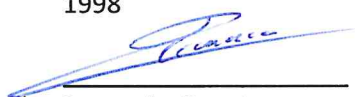
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