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: BE95/551137

CE certificate number: BE09/951042

Date CE Marking affixed: 1998

Signed:

Pasquale Cimmino,
CEO

Date: 22 JAN 2021

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