Declaration of Conformity

The manufacturer of the products covered by this Declaration is Polymer Science Inc. 2577 South Freeman Road Monticello, Indiana, USA 47960. The product is exclusively distributed by Safeguard Medical Technologies The Old Rectory, Hope-Under-Dinmore, Herefordshire HR6 0PW. Authorized representative established in the community is mdi Europa, Langenhagener Str. 71, 30855 Lageenhagen, Germany. The Notified Body is BSI Group, Say Building, 1066 EP Amsterdam, The Netherlands.

The Directives Covered by this Declaration
Directive 93/42/EEC of the European Communities and of the council of 14 June 1993 concerning medical devices.

The Products Covered by this Declaration
BCS Bolin Chest Seal
Occlusive hydrogel wound dressing of Class IIb for open chest injuries NSN 6510-01-549-0939

H-Vent (HVS01-CE and HVSO2-CE)
Occlusive hydrogel wound dressing of Class IIb for open chest injuries

Wound Seal kit (HHWSK02-CE)
Occlusive hydrogel wound dressing of Class IIb for open chest injuries NSN 6510-01-573-0300

DualSeal (HHDSK01-CE)
Pair of occlusive hydrogel wound dressings of Class IIb for open chest injuries

Complies with the Given CE Directives
Annex II of the directive 93/42/EEC – medical devices, as amended by Amending Directive 2007/47/EC of European Parliament and of the Council of 5 September 2007.

List of Technical Standards, Specifications, and Harmonized Norms used for Review of its Conformity
ISO 9001:2015 Quality management systems – Requirements
EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2003)
ISO 11137-1:2015 + A2:2019 Sterilization of health care products – Radiation Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices – Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/AMD 2:2018)
ISO 11137-2:2013 Sterilization of health care products – Radiation –Part 2: Establishing the Sterilization dose
ISO 11137-3:2017 Sterilization of health care products – Radiation – Part 3 – Guidance on dosimetric aspects of development, validation, and routine control
EN ISO 15223-1:2016 Medical Devices. Symbols to be used with medical device labels, labeling, and information to be supplied. General requirements.
ANSI/AAMI/ISO 11737-1:2018/AMD1:2021 Sterilization of Health Care Products – Microbiological methods – Part 1: Determination of population of microorganisms on products – Amendment 1
ANSI/AAMI/ISO 11737-2:2019 Sterilization of Health Care Products – Microbiological methods –Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process.
USP 41/NF 36 United States Pharmacopeia/National Formulary 2018
EN ISO 14971:2019 Medical Devices. Application of risk management to medical devices.
EN ISO 11607-1:2019: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems
EN ISO 10993-1: 2018 Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2006 Biological Evaluation of medical devices. Animal welfare requirements.
EN ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:1999)
EN ISO 10993-10:2013 Tests for irritation and sensitization
EN ISO 10993-12:2021 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials

Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animals Resources, National Research Council, National Academy Press, 1996
Association for Assessment and Accreditation for Laboratory Animal Care International (AAALAC)
American College of Surgeons, committee on Trauma. Advance Life Support, ISBN: 9781880696149, ACS 7th edition, 2004.
Naval Medical Research Center/Walter Reed Army Institute of Research Institutional Animal Care and Use Committee utilizes non-government standards including ASTM and ISO

The Basis on which Conformity is being Declared
The manufacturer hereby declares under his sole responsibility that the product identified above complies with the protection requirements of the Directive and with the principal elements of the above standards applied.
The technical documentation required to demonstrate that the product meets the requirements of the directive has been compiled and is available for inspection by the relevant enforcement authorities. The CE mark was first applied in 2009.
This certificate will remain valid until approved design change, but until May 26, 2024 at the latest.

Jennifer Bohan

January 17, 2024

Jennifer Bohan

Date

Quality Manager

Polymer Science, Inc.