DECLARATION OF CONFORMITY

For the Surgical Skin Marker

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Surgical Skin Marker
Legal Manufacturer:	Viomedex Ltd, Units 13 Swan Barn Business Centre, Old Swan Lane, Hailsham, East Sussex, BN27 2BY, United Kingdom
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Viomedex Surgical Skin Marker is a sterile, single use surgical instrument for clinical markings in a non- toxic violet ink.
MDD Classification:	Class Is
Notified Body:	Ente Certificazione Macchine S.r.l. Via Ca' Bella, 243, 40053 Valsamoggia, Loc. Castello di Serravalle (BO) Italy With Notified Body number: 1282
CE Certificate Reference:	ECM20MDD025
EU Authorised Representative:	Advena Limited, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
MDD Conformity Assessment Route:	Annex V of the Medical Device Directive 93/42/EEC - EC Declaration of Conformity (Production Quality Assurance)

Name Simon Travers **Position** Group Head of Quality Assurance and Regulatory Affairs

Signed  **Date** 14th January 2021

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standards No.	Standards Organization	Standards Title
EN 1041:2008+A1:2013	BS EN	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	EN ISO	Biological evaluation of medical devices. Evaluation & testing within a risk management process (BS EN ISO 10993 1:2009) EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009	EN ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-10:2010	EN ISO	Biological Evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-12:2012	EN ISO	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
EN ISO 13485:2016	EN ISO	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14155:2011	EN ISO	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	EN ISO	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	EN ISO	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 11137-1:2015	EN ISO	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
EN ISO 11137-2:2015	EN ISO	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
EN ISO 11737-1:2006	EN ISO	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)
EN ISO 11737-2:2009	EN ISO	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
EN ISO 11607-1:2009	EN ISO	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)
BS EN 868-5:2009	BS EN	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods

Standards No.	Standards Organization	Standards Title
ASTM F1929-15	N/A	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

Appendix II – Product Listing/Schedule

Part No	Description	GMDN Code
VX100	Bold Line Sterile Surgical Skin Marker	64415
VX110	Bold Line Sterile Surgical Skin Marker with Ruler	64415
VX200	Fine Line Sterile Surgical Skin Marker	64415
VX210	Fine Line Sterile Surgical Skin Marker with Ruler	64415
VX5100	Broad Line Sterile Surgical Skin Marker	64415
VX5110	Broad Line Sterile Surgical Skin Marker with Ruler	64415
VX110/5	Bold Line Sterile Surgical Skin Marker with Ruler (Packed in 5s)	64415
VX210/5	Fine Line Sterile Surgical Skin Marker with ruler (Packed in 5s)	64415
VX5110/5	Broad Line Sterile Surgical Skin Marker with Ruler (Packed in 5s)	64415