UNISIS CORP. JAPAN
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E-Mail: o-sales@unisis.co.jp

EC DECLARATION OF CONFORMITY

Manufacturer:	UNISIS CORP. 2675-1 Nishikata Koshigaya-shi Saitama 343-0822, Japan
European Representative:	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Product:	Needles, Spinal UNIEVER DISPOSABLE SPINAL ANESTHESIA NEEDLE Model: K-3 Lancet Point, Pencil Point K-3 Lancet Point (NRFit), Pencil Point (NRFit) Description: Refer to attached sheet 1
Classification:	Class III Rule 6 according to Annex IX of the MDD
Conformity Assessment Route:	Annex II applied

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:	Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
Standards:	Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are as per Attached sheet 2.
Notified Body:	SGS Belgium NV (Notified Body No. 1639) SGS House Noor derlaan 87 2030 Antwerp Belgium
EC Certificate:	Standard: EN ISO 13485:2016 EC Certificate #: JP19/030582 Issue 4 EC Design Examination Certificate #: JP19/040524 Issue 1 Issued by: SGS Belgium NV
Production Facilities:	Unisis Corp. Saitama Plant 2675-1 Nishikata Koshigaya-shi Saitama 343-0822, Japan Unisis Corp. Logistics / Sterilization Center 2623-1 Nishikata Koshigaya-shi, Saitama 343-0822, Japan

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Production Facilities: (Continued)	Unisis Corp. Hokkaido Plant 1-2-8 Wattsu Industrial Complex, Kita-Hiroshima City, Hokkaido 061-1281, Japan Yasui Co., Ltd. 2725 Kakusa, Kadogawa-cho, Higashiusuki-gun, Miyazaki 889-0697, Japan Kyowa seiko Inc. 2-1-19 Suwa, Iwatsuki-ku, Saitama-shi, Saitama 339-0007, Japan Ever Corporation 8-45 Sakitama, Nasushiobara-shi, Tochigi 325-0033, Japan
Sterilization Sites:	Unisis Corp. Logistics / Sterilization Center 2623-1 Nishikata Koshigaya-shi, Saitama 343-0822, Japan Japan Gas Co., Ltd. (Yokohama Sterilization Center) 2-7 Daikokucho, Tsurumi-ku, Yokohama-shi, Kanagawa 230-0053, Japan
Products covered:	This DOC is only valid in conjunction with batch specific confirmation of compliance documented in each batch release document.

This Declaration of Conformity is valid until 31st December, 2027 due to the extension of EC Certificate #JP19/030582 and EC Design Examination Certificate #JP19/040524 according to Regulation (EU) 2023/607.

Place, Date of issue: Saitama, July 7, 2023

Signature:

Yoshikazu Matsumoto
Manager, Regulatory Affairs Dept.

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UNIEVER DISPOSABLE SPINAL ANESTHESIA NEEDLE

>>Needle type

Model: K-3 Lancet Point, Pencil Point
Description: Drawing No.: DB-YKJ-SPI001-1
DB-YKJ-SPI001-2

Model: K-3 Lancet Point (NRFit), Pencil Point (NRFit)
Description: Drawing No.: DB-YKJ-SPI002-1

>> Packaging

Primary: Sterile pouch, Blister packaging
Drawing no. DB-YKJ-SPI001-3

Secondary: Box
Drawing no. DB-YKJ-SPI001-4 (K-3 Lancet Point, Pencil Point)
Drawing no. DB-YKJ-SPI002-2 (K-3 Lancet Point (NRFit), Pencil Point (NRFit))

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Attached sheet 2

LIST OF STANDARDS FOR UNIEVER DISPOSABLE SPINAL ANESTHESIA NEEDLE

Standard No.	Description
EN ISO 13485:2016 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
BS EN ISO 11135:2014 (ISO 11135:2014)	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
BS EN556-1:2001	Sterilization of medical devices. Requirements for medical devices to be designated 'Sterile'. Requirements for terminally sterilized medical devices
BS EN ISO 11607-1:2020 (ISO 11607-1:2019)	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2:2020 (ISO 11607-2:2019)	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes
EN ISO 15223-1:2016 (ISO 15223-1:2016)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied -Part 1: General requirement
BS EN 1041:2008	Information supplied by the manufacturer with medical devices
BS EN ISO 11737-1:2018	Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products
BS EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
BS EN 62366:2008	Medical devices. Application of usability engineering to medical devices
BS EN ISO 7864:2016 (ISO 7864:2016)	Sterile hypodermic needles for single use. Requirements and test methods
BS EN ISO 10993-1:2009 (ISO 10993-1:2009)	Biological evaluation of medical devices. Evaluation and testing within a risk management process
BS EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
BS EN ISO 10993-7:2008 (ISO10993-7:2008 (Cor1:2009))	Biological evaluation of medical devices. Ethylene oxide sterilization residuals
BS EN ISO 10993-10:2013 (ISO 10993-10:2010)	Biological evaluation of medical devices. Tests for irritation and skin sensitization
BS EN 20594-1:1994 (ISO 594-1:1986)	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. General requirements
ISO 9626:2016	Stainless Steel Needle Tubing
BS EN ISO 14644-1:2015 (ISO 14644-1:2015)	Cleanrooms and associated controlled environments. Classification of air cleanliness
BS EN ISO 14644-2:2015 (ISO 14644-2:2015)	Cleanrooms and associated controlled environments. Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration