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Self-Declaration for the Compliance with the Criteria Set Out in REGULATION (EU) 2023/607 For the Extension of the Validity of CE Certificates

UNISIS Corp.
2675-1 Nishikata, Koshigaya-Shi, Saitama, 343-0822 Japan
SRN: JP-MF-000026339

The CE Certificates issued by SGS Belgium NV, JP19/030582 issued on 24th October 2011 expired on 24th October 2022, JP19/040523 issued on 16th December 2011 expired on 16th December 2021and JP19/040524 issued on 22nd May 2012 expired on 6th August 2022, prior to the date of entry of the amendment, 20th March 2023.
Prior to the expiration of the CE Certificate, the manufacturer, UNISIS Corp., had a written agreement in place on 21st September, 2021 with the notified body, DEKRA Certification, Arnhem, the Netherlands for the conformity assessment of the devices including the appendix A.

The risk classes of the devices are Class III, Class IIa, Class IIb and Class Is according to Regulation (EU) 2017/745. Therefore, validity of certificate JP19/040524 and JP19/040523 are extended through on 31st December, 2027 and JP19/030582 is extended through on 31st December, 2028 according to REGULATION (EU) 2023/607.

The Notified Body, SGS Belgium NV (NB1639) that issued the CE Certificates, JP19/030582, JP19/040523 and JP19/040524 will remain responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices that it has certified.

UNISIS Corp. declares that the following criteria set out in REGULATION (EU) 2023/607 are met to make them eligible for the extension of the validity of the CE Certificate;

- ✓ QMS is in place in accordance with Article 10(9) MDR no later than 26 May 2024
- ✓ Application was lodged with a NB (or planned to be lodged by 26 May 2024) and an agreement was signed (or planned to be signed by 26 September 2024)
- ✓ There are no significant changes in the design
- ✓ There is no change in the intended use of the devices
- ✓ The devices do not present an unacceptable risk.
- ✓ The devices continue to comply with Directive 90/385/EEC AIMDD/Directive 93/42/EEC MDD, as applicable.
- ✓ The MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are met.
- ✓ Notified Body responsible for the surveillance of the devices

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Name: Yoshikazu Matsumoto Position: Manager of RA Dept.

Place: Saitama, Japan Date: June 21, 2023

Signature:

Appendix A – List of Devices Benefitting from Extension of the Validity of CE Certificates

Product Details, Names or Trade Names [As found of the DoC]	NB Number	Certificate Number	Classification [MDD]	Classification [MDR]
UNIEVER DISPOSABLE SPINAL ANESTHESIA NEEDLE	CE1639	JP19/030582 JP19/040524	Class III	Class III
UNIEVER DISPOSABLE COMBINED SPINAL EPIDURAL ANESTHESIA MINITRAY	CE1639	JP19/030582 JP19/040523	Class III	Class III
UNIEVER DISPOSABLE EPIDURAL ANESTHESIA MINITRAY	CE1639	JP19/030582	Class IIa	Class IIb
UNIEVER DISPOSABLE EPIDURAL ANESTHESIA NEEDLE	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE NERVE BLOCKADE NEEDLE	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE INTRODUCER	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE ANGIOGRAPHIC NEEDLE	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE BIOPSY NEEDLE	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE ATRAUMATIC MICRONEEDLE (TRIPLE TIP TYPE)	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE ATRAUMATIC MICRONEEDLE (SINGLE TIP TYPE)	CE1639	JP19/030582	Class IIa	Class IIa
UNIEVER DISPOSABLE LOSS OF RESISTANCE SYRINGE	CE1639	JP19/030582	Class Is	Class Is