UNISIS CORP.
2675-1 Nishikata, Koshigaya-shi,
Saitama 343-0822,
Japan

24 July 2023

Confirmation Letter Reference: CLNB1639 - JP/YOK/8093

To whom it may concern,

Confirmation that the manufacturer has presented the evidence of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, DEKRA Certification B.V, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

UNISIS CORP.
2675-1 Nishikata, Koshigaya-shi,
Saitama 343-0822,
Japan
SRN Number (if available): JP-MF-000026339

Authorized representative:
ADVENA LTD.
Tower Business Centre, 2nd FLR.,
Tower street, Swatar BKR 4013
Malta

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufactured provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR by the 16th Mar 2023.
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Pp [Sean Kelly]
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile single use epidural anaesthesia	Class IIb	N/A	JP19/030582

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
kit / Basic UDI-DI; 45894024403MTY5S			
Sterile single use combined spinal epidural anaesthesia kit / Basic UDI-DI; 45894024402CSE2N	Class III	N/A	JP19/030582 JP19/040523
Sterile single use spinal anaesthesia needle / Basic UDI-DI; 45894024401SPI4W	Class III	N/A	JP19/030582 JP19/040524
Sterile and non-sterile single use epidural anaesthesia needle and Sterile and non-sterile single use neve blockade needle / Basic UDI-DI; 45894024404EPI3D	Class IIa	N/A	JP19/030582
Sterile and non-sterile single use introducer / Basic UDI-DI; 45894024405INT4Q	Class IIa	N/A	JP19/030582
Sterile and non-sterile single use biopsy needle / Basic UDI-DI; 45894024406BPY4C	Class IIa	N/A	JP19/030582
Sterile single use injection needle / Basic UDI-DI; 45894024407MIC49	Class IIa	N/A	JP19/030582
Sterile single use loss of resistance syringe / Basic UDI-DI;	Class Is	N/A	JP19/030582

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
45894024410LOR4E			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/07/24	Version 1	Initial issue