Manufacturer's Declaration

in relation to Regulation 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ASAHI INTECC CO., LTD.
Manufacturer address and contact details	3-100 Akatsuki-cho, Seto Aichi 489-0071 Japan
Single Registration Number (SRN)	JP-MF-000010199

Authorised Representative name	Emergo Europe B.V.
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Single Registration Number (SRN)	NL-AR-000000116

Notified body name	DEKRA Certification B.V.
Notified body number	0344
Directive Certificate number(s) to which this confirmation is made	2107788CE23/2107788DE19
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	05 July 2023
End date of extended validity/transition period	31 December 2027

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached list and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached list

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☑ Expired/expires *after* 20 March 2023:

☑ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached list or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☑ A QMS in accordance with Article 10(9) MDR is in place.

  ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached list**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

ASAHI INTECC CO., LTD.

Aichi, Japan, 17 August 2023

Place and date of issue

Yasuyuki Kawahara
Person responsible for regulatory compliance

List of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device	
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6S80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6S
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6SL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6S110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6A80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6A
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6AL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 6Fr	WAIN-FBK-6A110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7S80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7S
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7SL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7S110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7A80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7A
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7AL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 7Fr	WAIN-FBK-7A110
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8S80
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8S
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8SL
ASAHI FUBUKI Neurovascular Guide Catheter ASAHI FUBUKI 8Fr	WAIN-FBK-8S110

Revision History

Ver.	Date	Description
1	8 June 2023	Newly established
2	17 August 2023	Removal of the catalog numbers for stiff type. Change of end date of extended validity/transition period due to the completion of MDR application agreement with the notified body.