ASAHI INTECC EUROPE B.V.
Head Office // Strawinskylaan 1461 (WTC Tower 10 - 14th floor) 1077 XX Amsterdam, The Netherlands (Tel)+31.20.794.0640 (Fax)+31.20.794.0641

January 30, 2023

DECLARATION OF APPLICABILITY OF THE TRANSITIONAL PROVISIONS TO LEGACY DEVICES

To whom it may concern,

This letter in order to declare that the following medical devices: (see Attachment 1), identified with the lot number and expiry date: described in the Attachment 2, whose manufacturer in accordance with COUNCIL DIRECTIVE 93/42/EEC ("MDD") is ASAHI INTECC CO., LTD., having its registered offices at 3-100 Akatsuki-cho, Seto-shi, Aichi 489-0071, Japan, have been manufactured, transferred to the importer, ASAHI INTECC EUROPE B.V., having its registered offices at Strawinskylaan 1461, 1077 XX, Amsterdam, the Netherlands, and placed on the market through a first supply, intended for distribution to EU and EEA distributors **before the expiry date of the CE marking certificate** according to MDD certificate number (please see below), foreseen on February 1, 2023.

For the avoidance of doubt, we declare that the ownership of and title to the medical devices described in the Attachment 1 has already been transferred to ASAHI INTECC EUROPE B.V. before the expiry date of the CE marking certificate of such devices.

Applicable Medical Devices and Certificate Number:

Product Name	Catalog Code	Certificate Date
ASAHI Peripheral Guide Wire Treasure 12	PAGH18M070	01/02/2023
	PAGH18M370	
ASAHI Peripheral Guide Wire Astato 30	PAGH18M071	
	PAGH18M371	
ASAHI Peripheral Guide Wire Regalia XS 1.0	PAGP140000	
	PAGP140300	
ASAHI Peripheral Guide Wire Astato XS 20	PAGH143092	
	PAGH143392	
ASAHI Peripheral Guide Wire Treasure Floppy	PAGH18M072	
	PAGH18M372	
ASAHI Peripheral Guide Wire ASAHI Gladius	PPW14R100S	
	PPW14R200S	
	PPW14R300S	
	PPW18R100S	
	PPW18R200S	
	PPW18R300S	
	PPW14R100P	
	PPW14R200P	
	PPW14R300P	
	PPW18R100P	
	PPW18R200P	
	PPW18R300P	

ASAHI Peripheral Guide Wire ASAHI Halberd	PHW14R101S	01/02/2023
	PHW14R201S	
	PHW14R301S	
	PHW18R101S	
	PHW18R201S	
	PHW18R301S	
	PHW14R101P	
	PHW14R201P	
	PHW14R301P	
	PHW18R101P	
	PHW18R201P	
	PHW18R301P	
ASAHI Peripheral Guide Wire ASAHI Gaia PV	PHW18R102S	
	PHW18R202S	
	PHW18R302S	
	PHW18R102P	
	PHW18R202P	
	PHW18R302P	
ASAHI Peripheral Guide Wire Astato XS 40	PAGHW143094	
	PAGHW143394	
ASAHI Peripheral Guide Wire ASAHI Gladius MG14 PV	PP14R003P	
	PP14R203P	
	PP14R303P	
	PP14R003S	
	PP14R203S	
	PP14R303S	
ASAHI Peripheral Guide Wire ASAHI Gladius MG14 PV ES	PP14R004P	
	PP14R204P	
	PP14R304P	
	PP14R004S	
	PP14R204S	
	PP14R304S	
ASAHI Peripheral Guide Wire ASAHI Gladius MG18 PV ES	PP18R004P	
	PP18R204P	
	PP18R304P	
	PP18R004S	
	PP18R204S	
	PP18R304S	

Consequently, in accordance with the European Commission, 15/02/2021 version 1.2, Management of Legacy Device, they are **legacy devices.**

Legacy devices are regulated in Chapter X – Final provisions, Article 120, paragraphs 2, 3 and 4 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and

93/42/EEC, as amended ("MDR"):

"2. […] Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 **shall remain valid until the end of the period indicated on the certificate**, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

3. […] a device which has a certificate that was issued in accordance with […] Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be **placed on the market** or put into service **until 26 May 2024**, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraph 3 of this Article, may continue to be **made available on the market** or put into service **until 26 May 2025.**"

In conclusion:

- The above devices were placed on the market before the expiry of the certificate according to MDD;
- The aforementioned devices have not undergone significant changes in the design and intended use;
- The manufacturer meets the requirements of MDR on post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices:

Hence, they can continue to be **made available on the market until 26 May 2025,** as long as the sterilization period has not expired.

Very truly yours,

ASAHI INTECC EUROPE B.V.

By: _____
Name: Manabu Sakamoto
Title: Representative Director

Attachment

- Attachment 1: List of lots for each code
- Attachment 2 Shipping Documents