

April 15, 2022

Dear Valued ASAHI INTECC Customer,

We, ASAHI INTECC Group, would like to inform you that the following devices (which have been renewed under the Directive 93/42/EEC (“MDD”)) may expire before new certificates are issued under the Regulation 2017/745 dated 5 April 2017 (“MDR”).

Product Name	Catalog Code	Certificate Date
ASAHI PTCA Guide Wire Fielder	AGP140000	12/08/2022
	AGP140300	
	AGP140000J	
ASAHI PTCA Guide Wire Fielder XT	AGP140002	
	AGP140302	
ASAHI PTCA Guide Wire Fielder FC	AGP140001	
	AGP140001J	
	AGP140301	
	AGP140301J	
ASAHI PTCA Guide Wire Grand Slam	AG141002	
	AG141002J	
	AG141302	
	AG141302J	
ASAHI PTCA Guide Wire Rinato	AGH146000	
	AGH146000J	
	AGH146300	
	AGH146300J	
ASAHI PTCA Guide Wire Prowaterflex	AGH147000	
	AGH147000J	
	AGH147300	
ASAHI PTCA Guide Wire Miracle 3	AG14M050	
	AG14M050J	
	AG14M350	
	AG14M350J	
ASAHI PTCA Guide Wire Miracle 6	AG14M060	
	AG14M060J	
	AG14M360	

	AG14M360J	
ASAHI PTCA Guide Wire Miracle 12	AG14M070	
	AG14M070J	
ASAHI PTCA Guide Wire ULTIMATEbros 3	AHW14S003J	
	AHW14S003S	
	AHW14S303J	
	AHW14S303S	
ASAHI PTCA Guide Wire Conquest Pro	AGH143090	
	AGH143090J	
	AGH143390	
	AGH143390J	
ASAHI PTCA Guide Wire Conquest Pro 12	AGH143091	

Considering the above situation, we decided to continue to sell the above products certified under the MDD in accordance with the transitional provisions of the MDR.

We would like to explain the transitional provisions of the MDR, as we believe it is important for you to understand why we are allowed to continue to sell the products certified under the MDD during a certain period after the entry into force of the MDR.

Article 120(2) of the MDR states that certificates which have been issued in accordance with the MDD from 25 May 2017 will remain in force until the end of their validity period, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

Article 120(3) of the MDR states that a device with a certificate that was issued in accordance with the MDD and which is valid by virtue of Article 120(2) may only be placed on the market or put into service until 26 May 2024, provided that from the date of application of the MDR (i.e. 26 May 2021) it continues to comply with the MDD, and provided there are no significant changes in the design and intended purpose.

Article 120(4) of the MDR states that devices lawfully placed on the market pursuant to the MDD prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to Article 120(3) (see above), may continue to be made available on the market or put into service until 26 May 2025.

To sum up, devices certified under the MDD that have been placed on the market by the due date of each device in accordance with the above provisions of the MDR (“MDD Products”) may be made available on the market or put into service until 26 May 2025.

For the avoidance of doubt, we confirmed that the MDD Products which have reached the final users (e.g., hospital) as being ready for use until 26 May 2025 may be used by the final users on or after 27 May 2025 within the valid sterilization period of such MDD Products.

Considering the transitional provisions, we, ASAHI INTECC EUROPE B.V., as the importer according to the MDR, will purchase and import products certified under the MDD and store them properly in our warehouse in the Netherlands. You may continue to issue a purchasing order for the products in accordance with our price offer, general terms and conditions or a supply/distributorship agreement.

To clarify the transition timeline, we attach the sheet describing the transition timelines from the MDD to the MDR.

Should you need additional information regarding this matter, please do not hesitate to contact your local representative.

Thank you very much for your kind understanding.

Very truly yours,

ASAHI INTECC CO., LTD.

Title: General Manager of International Sales Department

