Core Values, Core Technologies

ALPINION
MEDICAL SYSTEMS

Date: 09th Nov, 2023
Place: Republic of Korea

Letter of Authorization

To may whom concerns

Herewith we, **Alpinion Medical Systems Co.,Ltd**. its business address at 2F-4F, 15, Magokjungang 14-ro, Gangseo-gu, Seoul, 07789, Republic of Korea as manufacturer confirm that **iComed Sp. Zoo Sp. K** is authorized service party of **Alpinion Medical Systems Co.,Ltd**. and who operates the task of the service for cases of "out of warranty" of Ultrasound diagnostic systems for **Alpinion Medical Systems Co.,Ltd**. under the regulation of MDR 2017/745.

● Company Information of iComed Sp. Zoo Sp. K

- Company name: iComed Sp. zoo Sp. K
- Co-CEO: Artur Marciniak, Piotr Skorek
- Address ul. Suwak 4 , 02-676 Warsaw, Poland
- VAT: 9512300974
- Web: www.icomed.pl

ALPINION MEDICAL SYSTEMS Co., Ltd.
Hyun Jong Park / CEO / PRESIDENT

ALPINION MEDICAL SYSTEMS Co., Ltd
2-4F, 15, Magokjungang 14-ro, Gangseo-gu,
Seoul, Republic of Korea
CEO / President PARK HYUNJONG

APPENDIX #1.

Article 13 General obligations of importers	6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints. 7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken. 8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative. 10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.
Article 14 General obligations of distributors	4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken. 5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request. 6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device. Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.
Article 25 Identification within the supply chain	1. Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

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Seoul, Republic of Korea
CEO / President PARK HYUNJONG