EU Certificate of Verification

MDSS GmbH hereby declares

that an Authorized Representative's Mandate according to the

EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out

in accordance with the requirements of the MDR on behalf of the Manufacturer:

ISD MEDITECH SDN. BHD.

No.3, Jalan PJS 3/2, Taman Medan

46000 Petaling Jaya, Selangor

MALAYSIA

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2024-08-09
(YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 801874

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first. It also expires with the issuance of a newer EU Certificate of Verification covering the same legislation.

Technical File	Generic Device Description/ Trade Name	GMDN or EMDN Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
TECHNICAL DOCUMENTATION FOR CONFORMITY TO THE ESSENTIAL SAFETY AND PERFORMANCE OF ULTRASOUND TRANSMISSION GEL AND ECG GEL Rev. 14	Ultrasound Transmission and ECG Gel Sky GEL®	15321	I	2. DoC MDR 2017-745 - Rev 04 signed 28 June 2024	N.A.	N.A.	DE/CA09/00202436
Technical File Ultrasound Paper Rev. 02	Ultrasound Paper SKYMED, Accu-Plus	61901	I	DoC MDR 2017-745 - Rev 01 signed 01 Aug 2024	N.A.	N.A.	DE/CA09/00203247

*The registration number has been issued by the German Competent Authority.