Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

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NIP 521-32-14-182 REGON 015249601

Warsaw, 14-08-2023

CERTIFICATE OF FREE SALE No. 583/2023

In reference to application for a certificate of free sale submitted by the

ECHO-SON S.A.
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
ULTRASOUND SCANNER	ALBIT

manufactured by:

ECHO-SON S.A.
Ul. Krańcowa 5, 24-100 Puławy, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of 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 (OJ L 117, 5.5.2017, p. 1) on the terms set out in this regulation. The export of the above-mentioned product is not prohibited.

PREZES URZĘDU REJESTRACJI WYROBÓW MEDYCZNYCH, PRODUKTÓW LECZNICZYCH I PRODUKTÓW BIOBÓJCZYCH

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)