



Certified Translation from Polish.

[Description: This translation is made from a one-page document printed on a letterhead paper. Translator's notes are in square brackets.]



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

Department of Supervision and Clinical Trials of Medical Devices

Doc. ref. No. DNB.415.16.2023.6.TKR

Warsaw, April 23, 2026

ECHO-SON S.A.

Krańcowa 5

24-100 Puławy

In response to the letter dated April 22, 2026 regarding the extension of the deadline for eliminating the non-compliance referred to in the request under Article 97 paragraph 1 of the Regulation (EU) 2017/745 of the European Parliament and Council dated April 5, 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 (Journal of Laws EU No. L 117 of 05/05/2017, p. 1, as amended) of June 9, 2023, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products hereby informs as follows.

The President of the Office does not oppose the continued marketing and use of the following diagnostic ultrasound devices:

1. ALBIT ultrasound scanner
2. PINIT ultrasound scanner
3. PIROP biometric ultrasound scanner
4. OA12 probe
5. OB12 probe
6. OP20 probe
7. S 255B probe
8. CA 255 probe



9. LA 510 probe

10. R510 probe,

which were covered by a Certificate No. 5-824-200-1707 issued in accordance with Directive 93/42/EEC, until October 30, 2026, by which date the identified non-compliance must be remedied. The manufacturer is also obligated to immediately inform the President of the Office of the progress in the certification process, including the issuance of an EU Certificate of Conformity for the aforementioned products.

Authorized by the President,

Tomasz Koeber

Chief Specialist

/document signed electronically/

tel. +48 22 492-11-00,

e-mail address: urpl@urpl.gov.pl

website: urpl.gov.pl

GDPR - Information on the processing of personal data is available on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (<http://urpl.gov.pl/pl/daneosobowe>).

Aleje Jerozolimskie 181c
02-222 Warsaw

I confirm that this is a true translation consistent with the document in Polish presented to me.

Puławy, 24/04/2026.

Register number 384/2026.

Ewa Lipowska-Szymańska, MA

Entered in the Register of Sworn Translators maintained by the Minister of Justice under number: TP/164/05.

Ewa Lipowska-Szymańska
**SWORN TRANSLATOR
OF ENGLISH**

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-824-200-1707

The Directorate of Device Testing and Clinical Engineering (EMKI)
certifies that the manufacturer:

Echo-Son S. A.
ul. Krańcowa 5
24-100 Puławy
Poland

for the products / product category:

Diagnostic ultrasound devices

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-130-2007**

This certificate is valid until **2022-07-30** supposed that the results of the regular yearly surveillance audits are satisfactory.

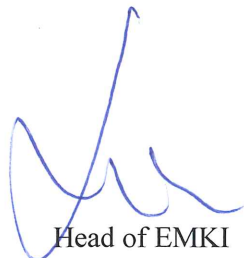
Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 2

First issued: 2017-07-31

Budapest, 2020-01-10


Head of EMKI



EMKI 2323

The authenticity and validity of the certificate are verifiable at EMKI.

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-824-200-1707

The certificate is valid for the following IIA products:

Diagnostic ultrasound devices

Ultrasound scanners:

ALBIT
EPIDOT SC
PINIT
SPINEL II

Ultrasound biometric scanner:

PIROP
PRAZ

Ultrasound biomicroscope:

EPIDOT / UMB

Probes:

OA12, OB12, OP20;
S255, S255B, S510, SM510, SS35;
V510; 2R575, R510;
CA305, CA255, CA409, CV580;
LA575, LA510, LA912

The detailed description of the products is kept by EMKI under No. 42-130-2007.

Issue: 2

Date: 2020-01-10

First issued: 2017-07-31



Head of EMKI



EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
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E-mail: cert@emki.hu, Web: www.emki.hu

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