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

Gyógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság

EMKI 2323

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

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering
H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 [illegible] 7733
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

Digitally signed by Bas Dumitru
Date: 2024.[illegible] 07 23:58:07 EET
Reason: MoldSign Signature
Location: Moldova

ATTACHMENT TO EC CERTIFICATE

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

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság

EMKI

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