

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.

Budapest, 2017-07-31



Head of EMKI



EMKI 1741

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 Ila products:

Diagnostic ultrasound devices

Ultrasound scanners:

ALBIT
EPIDOT SC
PINIT
SPINEL II

Ultrasound biometric scanner:

PIROP

Ultrasound biomicroscope:

EPIDOT / UMB

Probes:

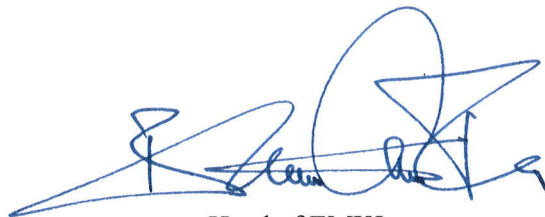
OA12, OB12, OP20;
S255, S255B, S510, SM510, SS35;
V510; 2R575, R510;
CA305, CA255, CA409, CV580;
LA575, LA510, LA912

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

Issue: 1

Date: 2017-07-31

First issued: 2017-07-31



Head of EMKI



EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
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EMKI