











### **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







**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

Head of EMKI



First issued: 2017-07-31



**EMKI** 

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