



ECHOSON

EC – Declaration of Conformity

ECHO-SON S.A.

**Krańcowa 5
24-100 Puławy
POLAND**

Declares that the following medical devices :

ultrasound biometric scanner: **PIROP equipped with
probes OA-12, OB-12, OP-20 and trolley**

with serial numbers 21/nn/nn XX

class IIa, are in conformity with essential requirements of
EU Medical Device Directive MDD 93/42/EEC, 2007/47/EC.

Conformity assessment was performed according to **Annex II and VII**
of the ***EU Medical Device Directive*** by Notified Body Number 1011,
EMKI National Institute for Quality- and Organizational Development in
Healthcare and Medicines (EMKI 5-824-200-1707).

Comply with the following provisions apply to it standards:

EN 60601-1

EN 60601-1-4

EN 60601-1-2

EN-ISO 14971

EN 60601-2-37

EN 61157



Z. Woźniak, President

Puławy, 11.01.2021