

DECLARATION OF CONFORMITY no 01/08/EN

Manufacturer: ASTAR ABR
A.JĘDRZEJOWSKI, R.DZIENDZIEL S.J.

Address: UL. STRAŻACKA 81,
43-382, BIELSKO-BIAŁA, POLAND

Product name:
**Ultrasound therapy unit
Sonaris**

versions:

- (M)
- (S)

Classification:

Ultrasound Therapy Unit Sonaris with accessories:

- **class IIa** rule 11 – for phonophoresis function
rule 9 – for ultrasound therapy function

Declaration:

Manufacturer declares under his own responsibility that the product described above complies with the requirements of Council Directive 93/42/EEC for medical devices.

Conformity assessment procedure:

Annex II article 3 of EC Directive 93/42/EEC

Documentation of releasing a product to sell:

„Final tests card” form SM-KBK, version 1.1, updated on 18.05.2009, as a part of the Technical File of the device, considered together with this Declaration of Conformity.

EC certificate: HD 60027842 0001

QMS certificate: SX 60027845 0001



Bielsko-Biała, Poland, 03.12.2010

signature:

(Robert Dziendziel)