

Declaration of Conformity CE

Manufacturer:

AC INTERNATIONAL EAST Sp. z o.o.
ul. Dworcowa 38A,
44-190 Knurów
Polska

We declare under our sole responsibility that the medical device:

OSTIUM

Serial number.....

Meets all provisions of the directive 93/42/EEC according to medical devices.

The product meets the requirements of the Act of 20 May 2010 on medical devices as amended and related regulations of the Minister of Health.

Conformity assessment procedure: Annex VII Directive 93/42/EEC

The technical documentation is stored:

AC INTERNATIONAL EAST Sp. z o.o.
ul. Dworcowa 38A,
44-190 Knurów
Polska

The classification of the device compliant with annex IX directive 93/42/EEC
Class I rule 1

Knurów, 02.11.2013 r.

PREZES
mgr inż. Rafał Kowalik