EC Declaration of Conformity

CE 2292

for the product

Paclitaxel eluting Balloon Catheter - ELUTAX "3"

Manufacturer: **AR Baltic Medical UAB**
P. Luksio g. 5B
LT-08221 Vilnius / Lithuania

Intended use: treatment of atherosclerotic or fibrotic strictures by opening-up a blocked passage by using a balloon which is coated with paclitaxel and dextran.

Hereby we declare under our sole responsibility that the aforementioned products meet all applicable requirements of Annex I

EC Directive 93/42/EEC on Medical Devices

in the version valid at the date of issue of this declaration.

Evidence of conformity has been demonstrated according to the procedure of Annex II.3 in conjunction with Annex II.4 of Directive 93/42/EEC.

Classification risk: Class III

Route: Rule 13 of annex IX

GMDN Number: ELUTAX "3"-RX-C 62218 all other ELUTAX "3" 62551

EMDN Number: ELUTAX "3"-RX-C C010401020101, ELUTAX "3" C010402020101, U0399

Standards applied: see attachment

Notified Body: **UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi Sanayi ve Ticaret Limited Sirketi**
Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA
Ankara (Turkey)
Identification No. 2292

EC Certificate No. M.2018.106.9148 / valid through *(31.12.2027)*

EC Design Examination Certificate No. M.2018.106.9148-1 / valid through *(31.12.2027)*

This declaration is valid until *(31.12.2027)*.

Vilnius, ...

Alexander Ruebben (General Manager)

AR Baltic Medical, UAB