



CERTIFICATE

EC Certificate No. 1434-MDD-037/2020

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies,
that the quality assurance system in the organization:

BIOSENSORS EUROPE S.A.

**Rue de Lausanne 29, 1110 Morges,
Switzerland**

for the design, manufacture and final inspection of medical device
class III

**BioPath™ (014 and 035) Paclitaxel Eluting PTA Balloon Catheter
(OTW)**

*List of medical devices covered by this certificate is given in the Annex no. 1
to the EC-Design-examination Certificate No. 1434-MDD-038/2020*

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 2020-02-06 to 2024-05-27

The date of issue of the Certificate: 2020-02-06



Application No: 416/2019
Module: H2


mgr Anna Wyroba
Vice-President



Certificate No **1434-MDD-037/2020**
Issued under the Contract No **MD-245/2019**
Bears the PCBC hologram.
Warsaw, 2020-02-06