Medical
Brokers

DECLARATION OF CONFORMITY

Manufacturer: **Medical Brokers Adam Cieślak sp. j.**
Lipowa 1
95-100 Zgierz, Poland

Declares that the following products:

Endoirrigation needles
Type: 0.3 x 25 one side-opening, 0.3 x 25 two-side openings 0.5 x 25 one side-opening

marked CE are medical devices Class IIa, Rule 6, according to Annex 9 of the Council Directive MDD 93/42/EEC (changed by 2007/47/EC) and fulfill the essential requirements specified in Annex 1 of the above mentioned Council Directive.
The conformity assessment procedure was performed by Notifying Body No 2274 TUV NORD Polska Sp. z o. o. 40-085 Katowice, ul. Mickiewicza 29 on the basis of Annex V of the Council Directive MDD 93/42/EWG and the EC Certificate No TNP/MDD/0305/3540/2020 has been issued.
The products fulfill the requirements of the Polish Act of Medical Devices dated 20.05. 2010 r. (published in Dz. U. no 107, item 679).

The products fulfill the requirements of the following standards:
PN-EN ISO 10993-1:2010; PN-EN ISO 10993-10:2015-02; PN-EN ISO 10993-11:2018-08;
PN-EN ISO 10993-7:2009; PN-EN ISO 10993-7:2009/AC May 2010;
PN-EN ISO 10993-4:2018-02; PN-EN 868-5:2019-01; PN-EN 556-1:2002;
PN-EN 556-1:2002/AC Feb. 2011; PN-EN ISO 11607-1:2020-06;
PN-EN ISO 11607-2:2020-06; PN-EN ISO 7864:2016-12; PN-EN ISO 2859-1:2003;
PN-EN ISO 9626:2016-12; PN-EN ISO 6009:2016-12; PN-EN ISO 11737-1:2018-03;
PN-EN ISO 11737-2:2010; PN-EN ISO 11135:2014-08; PN-EN ISO 14971:2020-05;
PN-EN ISO15223-1:2017-02; PN-EN 1041/A1:2013-12;
PN-EN 62366-1:2015-07; PN-EN ISO 80369-1:2019-02; PN-EN ISO 14644-1:2016-03;
PN-EN ISO 14644-2:2016-03; PN-EN ISO 14644-3:2020-03; PN-EN ISO 14968-1:2014

The quality management fulfill the requirements of the standard: **PN-EN ISO 13485:2016-04**

UMDNS code: 20217

On behalf of „MEDICAL BROKERS" Adam Cieślak sp. j.

Adam Cieślak
General Manager

Zgierz, March 24th 2021