



00-496 WARSAW, POLAND,
7 Nowy Świat Street 14
tel: +48 22 625 32 15
tel/fax: +48 22 621 58

03-152 WARSAW, POLAND,
294 Modlińska Street
tel: +48 22 597 44 00
fax: +48 22 597 44 44

DECLARATION OF CONFORMITY

MANUFACTURER: BALTON Sp. z o.o.,
ul. Nowy Świat 7/14,
00-496 Warszawa, Poland

PRODUCTS: REDON type aspiration catheter,

CODE: KOR6F50, KOR8F50, KOR10F50, KOR12F50, KOR14F50,
KOR16F50, KOR18F50, KOR20F50, KOR22F50, KOR24F50, KOR26F50, KOR28F50,
KOR30F50, KOR32F50, KOR34F50, KOR36F50, KOR6F70, KOR8F70, KOR10F70,
KOR12F70, KOR14F70, KOR16F70, KOR18F70, KOR20F70, KOR22F70, KOR24F70,
KOR26F70, KOR28F70, KOR30F70, KOR32F70, KOR34F70, KOR36F70, KOR6F100,
KOR8F100, KOR10F100, KOR12F100, KOR14F100, KOR16F100, KOR18F100, KOR20F100,
KOR22F100, KOR24F100, KOR26F100, KOR28F100, KOR30F100, KOR32F100, KOR34F100,
KOR36F100, KOR6F110, KOR8F110, KOR10F110, KOR12F110, KOR14F110, KOR16F110,
KOR18F110, KOR20F110, KOR22F110, KOR24F110, KOR26F110, KOR28F110, KOR30F110,
KOR32F110, KOR34F110, KOR36F110, KOR6F120, KOR8F120, KOR10F120, KOR12F120,
KOR14F120, KOR16F120, KOR18F120, KOR20F120, KOR22F120, KOR24F120, KOR26F120,
KOR28F120, KOR30F120, KOR32F120, KOR34F120, KOR36F120, KOR6F150, KOR8F150,
KOR10F150, KOR12F150, KOR14F150, KOR16F150, KOR18F150, KOR20F150, KOR22F150,
KOR24F150, KOR26F150, KOR28F150, KOR30F150, KOR32F150, KOR34F150, KOR36F150

CLASSIFICATION: Class IIa, The invasive devices – Rule 7 according to Annex IX
MDD 93/42/EEC

UMDNS CODE: 18-757

I declare that I shall look after the proper application of the quality system earmarked for design, production and final inspection of the medical equipment stipulated below. I assure and declare that the aforementioned products meet requirements of Medical Device Directive 93/42/EEC concerning the medical equipment, and that I have familiarised myself with a result of the design documentation evaluation and that I have been authorised to place 'CE' mark.

STANDARDS APPLIED: The applicable sections of the following standards for safety were applied:

EN 556-1:2001/AC:2006, EN 1041:2008/A1:2013, EN 1618:1997, ISO 2859-1:1999/Amd1:2011,
EN ISO 10079-3:2009, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-4:2009, EN ISO 10993-5:2009,
EN ISO 10993-7:2008/AC:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2009, ISO 11135:2014,
EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN ISO 11737-1:2006/AC:2012,
EN ISO 13485:2012, EN ISO 13485:2012+AC:2012, EN ISO 14971:2012, EN 62366-1:2015

NOTIFIED BODY: TÜV Rheinland LGA Product GmbH,
Tillystraße 2, 90431 Nürnberg
Identification Number 0197,

CERTIFICATES: EN ISO 13485:2016 No SX 60126763 0001

EC CERTIFICATE: Approval EC Directive 93/42/EEC, Annex II, excluding Section 4
Quality Assurance System Production, No HD 60097877 0001

January 12, 2015
Warsaw, Poland

Emil Płowiecki
Chairman of Balton Sp. z o.o.



BALTON Sp. z o.o.
POLAND
00-496 Warsaw, 7 Nowy Świat Street, apt 14
tel. (48-22) 579 44 20; tel./fax: (48-22) 621 58 14
tel. (48-22) 597 44 10; tel./fax: (48-22) 597 44 44