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DECLARATION OF CONFORMITY

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

PRODUCTS: Embolectomy and trombectomy catheters,

CODE: EFB2F40, EFB2F60, EFB3F15, EFB3F40, EFB3F80, EFB4F15,
EFB4F40, EFB10F40, EFB10F80, EFB4F80, EFB5F40, EFB5F80,
EFB6F40, EFB6F80, EFB7F40, EFB7F80, EFB8F40, EFB8F80,
EFBD5F15, EFBD5F40, EFBD5F80, EFBD6F15, EFBD6F40,
EFBD6F80, EFBD7F40, EFBD7F80,

CLASSIFICATION: Class II a, The invasive devices – Rule 6 according to Annex IX
MDD 93/42/EEC

CODE: UMDNS – 20-422

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/Adm1:2011,
EN ISO 80369-7:2017, EN ISO 10555-1:2013, ISO 10555-3:2013, ISO 10555-4:2013,
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 11135:2014, EN ISO 11607-1:2017,
EN ISO 11607-2:2017, EN ISO 11737-1:2006/AC:2009, EN ISO 13485:2016, EN ISO 14971:2012,
EN ISO 15223-1:2016, 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

Warsaw, November 20rd, 2018

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