BALTON®

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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: **TŰV 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

Emil Plowiecki

Chairman of Balton Sp. z o.o.

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