BALTON®

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DECLARATION OF CONFORMITY

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

PRODUCTS: **Nephrostomy catheters and kits,**

CODE: **KNEF8F45, KNEF9F45, KNEF10F45, KNEF11F45, KNEF12F45, KNEF14F45, KNEF8F45PI, KNEF9F45PI, KNEF10F45PI, KNEF11F45PI, KNEF12F45PI, KNEF14F45PI, ZNEF8F, ZNEF9F, ZNEF10F, ZNEF11F, ZNEF12F, ZNEF14F, ZNEF8FPR, ZNEF9FPR, ZNEF10FPR, ZNEF11FPR, ZNEF12FPR, ZNEF14FPR, ZWK 8F, ZWK9F, ZWK10F, ZWK11F, ZWK12F, ZWK14F, KNPIG5F, KNPIG8F, KNPIG9F, KNPIGTR5F, KNPIGTR8F, KNPIGTR9F, SNEF5F, SNEF8F, SNEF9F, SNEF10F, SNEF12F**

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

UMDNS CODE: **10-735**

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 10993-1:2009/AC:2010, EN ISO 10993-3:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2009, 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 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 Płowiecki

Chairman of Balton Sp. z o.o.

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