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EC Declaration of Conformity

MANUFACTURER: **Balton Sp. z o.o.**
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The Medical Device: **Large vessels catheterization catheters and kits,**

REFERENCE:

KKDN1.2F{from 5 to 32}IR; KKDN2F{from 5 to 32}IR, KKDN2F{from 5 to 20}; KKDN3, 4, 4.5F{from 5 to 45}; KKDN5, 5.5, 6, 7, 7.5, 8, 9, 10, 11F{from 5 to 60}; KKDND3, 4, 4.5, 5, 5.5, 6, 7, 7.5, 8, 8.5, 9, 10, 11F{from 5 to 30}; KKDNT4, 4.5, 5, 5.5, 6, 7, 8, 9, 11F{from 5 to 30}; KKDNIV7, 8, 8.5F{from 15 to 30};ZKDN1.2F{from 5 to 32}IR; ZKDN2F{from 5 to 32}IR; ZKDN2F{from 5 to 20}; ZKDN3, 4, 4.5F{from 5 to 45}; ZKDN2F{from 5 to 20}Y; ZKDN2F{from 5 to 20}SR; ZKDN2F{from 5 to 20}KLLT; ZKDN2F{from 5 to 20}KLLI; ZKDN2F{from 5 to 20}BL; ZKDN2F{from 5 to 20}V; ZKDN2F{from 5 to 20}E; ZKDN2F{from 5 to 20}IZK; ZKDN2F{from 5 to 20}YE; ZKDN2F{from 5 to 20}YSR; ZKDN2F{from 5 to 20}YEV; ZKDN2F{from 5 to 20}YV; ZKDN2F{from 5 to 20}YKLLT; ZKDN2F{from 5 to 20}YKLLI; ZKDN2F{from 5 to 20}YKLLTSR; ZKDN2F{from 5 to 20}YKLLISR; ZKDN2F{from 5 to 20}YKLLTSRE; ZKDN2F{from 5 to 20}YKLLISRE; ZKDN2F{from 5 to 20}YKLLTBL; ZKDN2F{from 5 to 20}YKLLIBL; ZKDN2F{from 5 to 20}YKLLTBLE; ZKDN2F{from 5 to 20}YKLLIBLE; ZKDN2F{from 5 to 20}YKLLTSRBLE; 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ZKDNIV7, 8, 8.5F{from 15 to 30}KLLIEIZK; ZKDNIV7, 8, 8.5F{from 15 to 30}KLLTBLEIZK; ZKDNIV7, 8, 8.5F{from 15 to 30}KLLIBLEIZK; ZKDNIV7, 8, 8.5F{from 15 to 30}KLLTBLSREIZK; ZKDNIV7, 8, 8.5F{from 15 to 30}KLLIBLSREIZK; ZKDNIV7, 8, 8.5F{from 15 to 30}KLLTSRE; ZKDNIV7, 8, 8.5F{from 15 to 30}KLLISRE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IY; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYEV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSR; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLLT; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLI; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTSR; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLISR; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTSRE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLISRE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTBL; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLIBL; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTBLE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLITBLE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTSRBLE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLISRBLE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSRV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSRE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSREV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIY; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYEV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYSR; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYSRE; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLYSREV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYSREV; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLYSREVIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLIIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTSRBLIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLISRBLIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLTSRBLEIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYKLLISRBLEIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSRIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSREIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYEIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYSREVIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}IYIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYEIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYEVIZK; ZKDNIV7, 8, 8.5F{FROM 15 TO 30}BLIYIZK.

CLASSIFICATION: **Class III, rule 7 according to Annex IX of 93/42/EEC Directive,**

CODE: **GMDN – 16615**

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 1707:1996,** **ISO 2859-1:1999/Amd1:2011, EN ISO 7864: 2016, EN ISO 9626:2016,** **EN ISO 10555-1:2013, EN ISO 10555-3:2013, EN ISO 10993-1:2009/AC:2010,** **EN ISO 10993-3:2014, 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,** **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 ISO15223-1: 2016,EN 20594-1:1993/AC:1996, EN 62366-1:2015**
NOTIFIED BODY:	**CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.** **Gyár u. 2.** **2040 Budaörs** **Country : Hungary** **Identification number: 2409**
CERTIFICATES:	**EN ISO 13485:2016 No SX 60126763 0001,**
EC CERTIFICATES:	**EC Certificate according to Annex II excluding 4 of Council Directive 93/42/EEC No 144612-16-03-25** **EC Design-Examination Certificate according to Annex II Section 4 of Council Directive 93/42/EEC, No 144734-18-03-27**

April 04, 2018
Warsaw, Poland

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