



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

Large vessels catheterization catheters and kits.

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}; KKDND3, 4, 4.5, 5, 5.5, 6, 7, 7.5, 8, 8.5, 9, 10, 11F{from 5 to 60}; KKDNIV7, 8, 8.5F{from 5 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}YKLLTSRBL; ZKDN2F{from 5 to 20}YKLLISRBL; ZKDN2F{from 5 to 20}YKLLITZK; ZKDN2F{from 5 to 20}YKLLIIZK; ZKDN2F{from 5 to 20}YKLLTSRBLIZK; ZKDN2F{from 5 to 20}YKLLISRBLIZK; ZKDN2F{from 5 to 20}YKLLTSRBLEIZK; ZKDN2F{from 5 to 20}YKLLISRBLEIZK; ZKDN2F{from 5 to 20}YSRIZK; ZKDN2F{from 5 to 20}YSREIZK; ZKDN2F{from 5 to 20}YEIZK; ZKDN2F{from 5 to 20}YSREVIZK; ZKDN2F{from 5 to 20}BLEYIZK; ZKDN2F{from 5 to 20}YIZK; ZKDN2F{from 5 to 20}YSRV; ZKDN2F{from 5 to 20}YSRE; ZKDN2F{from 5 to 20}YSEV; ZKDN2F{from 5 to 20}BLY; ZKDN2F{from 5 to 20}BLE; ZKDN2F{from 5 to 20}BLYEIZK; ZKDN2F{from 5 to 20}BLYEVIZK; ZKDN2F{from 5 to 20}BLIZK; ZKDN2F{from 5 to 20}BLYIZK; ZKDN2F{from 5 to 20}BLEIZK; ZKDN2F{from 5 to 20}BLEVIZK; ZKDN2F{from 5 to 20}BLV; ZKDN2F{from 5 to 20}BLEV; ZKDN2F{from 5 to 20}BLYV; ZKDN2F{from 5 to 20}BLYEV; ZKDN2F{from 5 to 20}BLSRE; ZKDN2F{from 5 to 20}BLSREV; ZKDN2F{from 5 to 20}BLSR; ZKDN2F{from 5 to 20}BLYSR; ZKDN2F{from 5 to 20}BLYSRE; ZKDN2F{from 5 to 20}SRV; ZKDN2F{from 5 to 20}SRE; ZKDN2F{from 5 to 20}SREV; ZKDN2F{from 5 to 20}SRIZK; ZKDN2F{from 5 to 20}SREIZK; ZKDN2F{from 5 to 20}SREVIZK; ZKDN2F{from 5 to 20}EV; ZKDN2F{from 5 to 20}KLLTE; ZKDN2F{from 5 to 20}KLLIE; ZKDN2F{from 5 to 20}KLLTBL; ZKDN2F{from 5 to 20}KLLIBL; ZKDN2F{from 5 to 20}KLLTBLE; ZKDN2F{from 5 to 20}KLLIBLE; ZKDN2F{from 5 to 20}KLLTBLSR; ZKDN2F{from 5 to 20}KLLIBLSR; ZKDN2F{from 5 to 20}KLLTBSLRE; ZKDN2F{from 5 to 20}KLLIBLSRE; ZKDN2F{from 5 to 20}KLLIE; ZKDN2F{from 5 to 20}KLLI; ZKDN2F{from 5 to 20}KLLTSR; ZKDN2F{from 5 to 20}KLLISR; ZKDN2F{from 5 to 20}KLLIEIZK; ZKDN2F{from 5 to 20}KLLIEIZK; ZKDN2F{from 5 to 20}KLLTBLEIZK; ZKDN2F{from 5 to 20}KLLIBLEIZK; ZKDN2F{from 5 to 20}KLLTBSLEIZK; ZKDN2F{from 5 to 20}KLLIBLSREIZK; ZKDN2F{from 5 to 20}KLLIBLSREIZK; ZKDN2F{from 5 to 20}KLLTSRE; ZKDN2F{from 5 to 20}KLLISRE; ZKDN3, 4, 4.5F{from 5 to 45}Y; ZKDN3, 4, 4.5F{from 5 to 45}SR; ZKDN3, 4, 4.5F{from 5 to 45}KLLT; ZKDN3, 4, 4.5F{from 5 to 45}KLLI; ZKDN3, 4, 4.5F{from 5 to 45}BL; ZKDN3, 4, 4.5F{from 5 to 45}V; ZKDN3, 4, 4.5F{from 5 to 45}E; ZKDN3, 4, 4.5F{from 5 to 45}IZK; ZKDN3, 4, 4.5F{from 5 to 45}YE; ZKDN3, 4, 4.5F{from 5 to 45}YSR; ZKDN3, 4, 4.5F{from 5 to 45}YEV; ZKDN3, 4, 4.5F{from 5 to 45}YV; ZKDN3, 4, 4.5F{from 5 to 45}YKLLT; ZKDN3, 4, 4.5F{from 5 to 45}YKLLI; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTSR; ZKDN3, 4, 4.5F{from 5 to 45}YKLLISR; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTSRE; ZKDN3, 4, 4.5F{from 5 to 45}YKLLISRE; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTBL; ZKDN3, 4, 4.5F{from 5 to 45}YKLLIBL; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTBLE; ZKDN3, 4, 4.5F{from 5 to 45}YKLLIBLE; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTSRBL; ZKDN3, 4, 4.5F{from 5 to 45}YKLLISRBL; ZKDN3, 4, 4.5F{from 5 to 45}YKLLITZK; ZKDN3, 4, 4.5F{from 5 to 45}YKLLISRBLIZK; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTSRBLIZK; ZKDN3, 4, 4.5F{from 5 to 45}YKLLISRBLIZK; ZKDN3, 4, 4.5F{from 5 to 45}YKLLTSRBLEIZK; ZKDN3, 4, 4.5F{from 5 to 45}YKLLISRBLEIZK; ZKDN3, 4, 4.5F{from 5 to 45}YSRIZK; ZKDN3, 4, 4.5F{from 5 to 45}YSREIZK; ZKDN3, 4, 4.5F{from 5 to 45}YEIZK; ZKDN3, 4, 4.5F{from 5 to 45}YSREVIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLEYIZK; ZKDN3, 4, 4.5F{from 5 to 45}YIZK; ZKDN3, 4, 4.5F{from 5 to 45}YSRV; ZKDN3, 4, 4.5F{from 5 to 45}YSRE; ZKDN3, 4, 4.5F{from 5 to 45}YSEV; ZKDN3, 4, 4.5F{from 5 to 45}BLY; ZKDN3, 4, 4.5F{from 5 to 45}BLE; ZKDN3, 4, 4.5F{from 5 to 45}BLYEIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLYEVIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLYIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLEIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLEVIZK; ZKDN3, 4, 4.5F{from 5 to 45}BLV; ZKDN3, 4, 4.5F{from 5 to 45}BLEV; ZKDN3, 4, 4.5F{from 5 to 45}BLYV; ZKDN3, 4, 4.5F{from 5 to 45}BLYEV; ZKDN3, 4, 4.5F{from 5 to 45}BLSRE; ZKDN3, 4, 4.5F{from 5 to 45}BLSREV; ZKDN3, 4, 4.5F{from 5 to 45}BLSR; ZKDN3, 4, 4.5F{from 5 to 45}BLYSR; ZKDN3, 4, 4.5F{from 5 to 45}BLYSRE; ZKDN3, 4, 4.5F{from 5 to 45}SRV; ZKDN3, 4, 4.5F{from 5 to 45}SRE; ZKDN3, 4, 4.5F{from 5 to 45}SREV; ZKDN3, 4, 4.5F{from 5 to 45}SRIZK; ZKDN3, 4, 4.5F{from 5 to 45}SREIZK; ZKDN3, 4, 4.5F{from 5 to 45}SREVIZK; ZKDN3, 4, 4.5F{from 5 to 45}EV; ZKDN3, 4, 4.5F{from 5 to 45}KLLTE; ZKDN3, 4, 4.5F{from 5 to 45}KLLIE; ZKDN3, 4, 4.5F{from 5 to 45}KLLTBL; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBL; ZKDN3, 4, 4.5F{from 5 to 45}KLLTBLE; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBLE; ZKDN3, 4, 4.5F{from 5 to 45}KLLTBLSR; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBLSR; ZKDN3, 4, 4.5F{from 5 to 45}KLLTBSLRE; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBLSRE; ZKDN3, 4, 4.5F{from 5 to 45}KLLIE; ZKDN3, 4, 4.5F{from 5 to 45}KLLI; ZKDN3, 4, 4.5F{from 5 to 45}KLLTSR; ZKDN3, 4, 4.5F{from 5 to 45}KLLISR; ZKDN3, 4, 4.5F{from 5 to 45}KLLIEIZK; ZKDN3, 4, 4.5F{from 5 to 45}KLLIEIZK; ZKDN3, 4, 4.5F{from 5 to 45}KLLTBLEIZK; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBLEIZK; ZKDN3, 4, 4.5F{from 5 to 45}KLLTBSLEIZK; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBLSREIZK; ZKDN3, 4, 4.5F{from 5 to 45}KLLIBLSREIZK; ZKDN3, 4, 4.5F

[illegible]

[illegible]

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

BALTON Sp. z o.o.
POLAND
00-498 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

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

