



00-496 WARSAW, POLAND,  
7 Nowy Świat Street 14  
tel: +48 22 625 32 15  
tel/fax: +48 22 621 58

03-152 WARSAW, POLAND,  
294 Modlińska Street  
tel: +48 22 597 44 00  
fax: +48 22 597 44 44

## EC Declaration of Conformity

**MANUFACTURER:**

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

**We declare under our sole responsibility that:**

**The Medical Device:**

**Dialysis catheters and kits,**

**Models:**

KDJP8F{from 10 to 30}; ZDJP8F{from 10 to 30}; KDJP8F{from 10 to 30}P;  
ZDJP8F{from 10 to 30}P; KDJP8F{from 10 to 30}S; ZDJP8F{from 10 to 30}S; KDJP8F{from 10 to 30}PS;  
ZDJP8F{from 10 to 30}PS; KDJP8F{from 10 to 30}Y; ZDJP8F{from 10 to 30}Y; KDJP8F{from 10 to 30}PY;  
ZDJP8F{from 10 to 30}PY; KDJP8F{from 10 to 30}SL; ZDJP8F{from 10 to 30}SL; KDJP8F{from 10 to 30}PSL;  
ZDJP8F{from 10 to 30}PSL; KDJP8F{from 10 to 30}KLLT; ZDJP8F{from 10 to 30}KLLT; KDJP8F{from 10 to 30}  
30}PKLLT; ZDJP8F{from 10 to 30}PKLLT; KDJP8F{from 10 to 30}KLLI; ZDJP8F{from 10 to 30}KLLI;  
KDJP8F{from 10 to 30}PKLLI; ZDJP8F{from 10 to 30}PKLLI; KDJP8F{from 10 to 30}PKLLI; KDJP8F{from 10 to 30}  
KDJP8F{15, 18, 20}P; ZDJP8F{15, 18, 20}P; KDJP8F{15, 18, 20}S; ZDJP8F{15, 18, 20}S; KDJP8F{15, 18,  
20}PS; ZDJP8F{15, 18, 20}PS; KDJP8F{15, 18, 20}PY; ZDJP8F{15, 18, 20}PY; KDJP8F{15, 18, 20}PY;  
ZDJP8F{15, 18, 20}PY; KDJP8F{15, 18, 20}SL; ZDJP8F{15, 18, 20}SL; KDJP8F{15, 18, 20}PSL; ZDJP8F{15,  
18, 20}PSL; KDJP8F{15, 18, 20}KLLT; ZDJP8F{15, 18, 20}KLLT; KDJP8F{15, 18, 20}PKLLT; ZDJP8F{15, 18,  
20}PKLLT; KDJP8F{15, 18, 20}KLLI; ZDJP8F{15, 18, 20}KLLI; KDJP8F{15, 18, 20}PKLLI; ZDJP8F{15, 18,  
20}PKLLI; KDJP8F{15, 18, 20}SR; ZDJP8F{15, 18, 20}SR; KDJP8F{15, 18, 20}PSR; ZDJP8F{15, 18, 20}PSR;  
KDD6.5, 7, 8F{from 7 to 20}; KDD6.5, 7, 8F{from 7 to 20}P; KDD6.5, 7, 8F{from 7 to 20}Z; KDD6.5, 7, 8F{from 7  
to 20}ZP; KDD9, 10F{from 10 to 20}; KDD9, 10F{from 10 to 20}P; KDD9, 10F{from 10 to 20}Z; KDD9, 10F{from  
10 to 20}ZP; KDD11, 11.5, 12, 13F{from 12 to 30}; KDD11, 11.5, 12, 13F{from 12 to 30}P; KDD11, 11.5, 12,  
13F{from 12 to 30}Z; KDD11, 11.5, 12, 13F{from 12 to 30}ZP; KDD6.5, 7, 8F{from 7 to 20}S; KDD6.5, 7, 8F{from 7  
to 20}PS; KDD6.5, 7, 8F{from 7 to 20}ZS; KDD6.5, 7, 8F{from 7 to 20}ZPS; KDD9, 10F{from 10 to 20}S; KDD9,  
10F{from 10 to 20}PS; KDD9, 10F{from 10 to 20}ZS; KDD9, 10F{from 10 to 20}ZPS; KDD11, 11.5, 12,  
13F{from 12 to 30}S; KDD11, 11.5, 12, 13F{from 12 to 30}PS; KDD11, 11.5, 12, 13F{from 12 to 30}ZS; KDD11, 11.5,  
12, 13F{from 12 to 30}ZPS; KDD6.5, 7, 8F{from 7 to 20}Y; KDD6.5, 7, 8F{from 7 to 20}PY; KDD6.5, 7, 8F{from 7  
to 20}ZY; KDD6.5, 7, 8F{from 7 to 20}ZPY; KDD9, 10F{from 10 to 20}Y; KDD9, 10F{from 10 to 20}PY; KDD9,  
10F{from 10 to 20}ZY; KDD9, 10F{from 10 to 20}ZPY; KDD11, 11.5, 12, 13F{from 12 to 30}Y; KDD11, 11.5, 12,  
13F{from 12 to 30}PY; KDD11, 11.5, 12, 13F{from 12 to 30}ZY; KDD11, 11.5, 12, 13F{from 12 to 30}ZPY; KDD6.5,  
7, 8F{from 7 to 20}KLLT; KDD6.5, 7, 8F{from 7 to 20}PKLLT; KDD6.5, 7, 8F{from 7 to 20}ZKLLT; KDD6.5, 7,  
8F{from 7 to 20}ZPKLLT; KDD9, 10F{from 10 to 20}KLLT; KDD9, 10F{from 10 to 20}PKLLT; KDD9, 10F{from  
10 to 20}ZKLLT; KDD9, 10F{from 10 to 20}ZPKLLT; KDD11, 11.5, 12, 13F{from 12 to 30}KLLT; KDD11, 11.5,  
12, 13F{from 12 to 30}PKLLT; KDD11, 11.5, 12, 13F{from 12 to 30}ZKLLT; KDD11, 11.5, 12, 13F{from 12 to  
30}ZPKLLT; KDD6.5, 7, 8F{from 7 to 20}SL; KDD6.5, 7, 8F{from 7 to 20}PSL; KDD6.5, 7, 8F{from 7 to 20}ZSL;  
KDD6.5, 7, 8F{from 7 to 20}ZPSL; KDD9, 10F{from 10 to 20}SL; KDD9, 10F{from 10 to 20}PSL; KDD9, 10F{from  
10 to 20}ZSL; KDD9, 10F{from 10 to 20}ZPSL; KDD11, 11.5, 12, 13F{from 12 to 30}SL; KDD11, 11.5, 12,  
13F{from 12 to 30}PSL; KDD11, 11.5, 12, 13F{from 12 to 30}ZSL; KDD11, 11.5, 12, 13F{from 12 to 30}ZPSL;  
KDD6.5, 7, 8F{from 7 to 20}KLLI; KDD6.5, 7, 8F{from 7 to 20}PKLLI; KDD6.5, 7, 8F{from 7 to 20}ZKLLI;  
KDD6.5, 7, 8F{from 7 to 20}ZPKLLI; KDD9, 10F{from 10 to 20}KLLI; KDD9, 10F{from 10 to 20}PKLLI; KDD9,  
10F{from 10 to 20}ZKLLI; KDD9, 10F{from 10 to 20}ZPKLLI; KDD11, 11.5, 12, 13F{from 12 to 30}KLLI; KDD11,  
11.5, 12, 13F{from 12 to 30}PKLLI; KDD11, 11.5, 12, 13F{from 12 to 30}ZKLLI; KDD11, 11.5, 12, 13F{from 12 to  
30}ZPKLLI; KDD6.5, 7, 8F{from 7 to 20}SR; KDD6.5, 7, 8F{from 7 to 20}PSR; KDD6.5, 7, 8F{from 7 to 20}ZSR;  
KDD6.5, 7, 8F{from 7 to 20}ZPSR; KDD9, 10F{from 10 to 20}SR; KDD9, 10F{from 10 to 20}PSR; KDD9,  
10F{from 10 to 20}ZSR; KDD9, 10F{from 10 to 20}ZPSR; KDD11, 11.5, 12, 13F{from 12 to 30}SR; KDD11, 11.5,  
12, 13F{from 12 to 30}PSR; KDD11, 11.5, 12, 13F{from 12 to 30}ZSR; KDD11, 11.5, 12, 13F{from 12 to 30}ZPSR;  
KDT12F{from 12 to 30}; KDT12F{from 12 to 30}P; KDT12F{from 12 to 30}Z; KDT12F{from 12 to 30}ZP;  
KDT12F{from 12 to 30}S; KDT12F{from 12 to 30}PS; KDT12F{from 12 to 30}ZS; KDT12F{from 12 to 30}ZPS;  
KDT12F{from 12 to 30}Y; KDT12F{from 12 to 30}PY; KDT12F{from 12 to 30}ZY; KDT12F{from 12 to 30}ZPY;  
KDT12F{from 12 to 30}KLLT; KDT12F{from 12 to 30}PKLLT; KDT12F{from 12 to 30}ZKLLT; KDT12F{from 12 to  
30}ZPKLLT; KDT12F{from 12 to 30}SL; KDT12F{from 12 to 30}PSL; KDT12F{from 12 to 30}ZSL;  
KDT12F{from 12 to 30}ZPSL; KDT12F{from 12 to 30}KLLI; KDT12F{from 12 to 30}PKLLI; KDT12F{from 12 to  
30}ZKLLI; KDT12F{from 12 to 30}ZPKLLI; KDT12F{from 12 to 30}SR; KDT12F{from 12 to 30}PSR;



KDT12F{from12 to 30}ZSR; KDT12F{from12 to 30}ZPSR; ZDD6.5, 7, 8F{from 7 to 20}; ZDD6.5, 7, 8F{from 7 to 20}P; ZDD6.5, 7, 8F{from 7 to 20}Z; ZDD6.5, 7, 8F{from 7 to 20}ZP; ZDD9, 10F{from 10 to 20}; ZDD9, 10F{from 10 to 20}P; ZDD9, 10F{from 10 to 20}Z; ZDD9, 10F{from 10 to 20}ZP; ZDD11, 11.5, 12, 13F{from12 to 30}; ZDD11, 11.5, 12, 13F{from12 to 30}P; ZDD11, 11.5, 12, 13F{from12 to 30}Z; ZDD11, 11.5, 12, 13F{from12 to 30}ZP; ZDD6.5, 7, 8F{from 7 to 20}S; ZDD6.5, 7, 8F{from 7 to 20}PS; ZDD6.5, 7, 8F{from 7 to 20}ZS; ZDD6.5, 7, 8F{from 7 to 20}ZPS; ZDD9, 10F{from 10 to 20}S; ZDD9, 10F{from 10 to 20}PS; ZDD9, 10F{from 10 to 20}ZS; ZDD9, 10F{from 10 to 20}ZPS; ZDD11, 11.5, 12, 13F{from12 to 30}S; ZDD11, 11.5, 12, 13F{from12 to 30}PS; ZDD11, 11.5, 12, 13F{from12 to 30}ZS; ZDD11, 11.5, 12, 13F{from12 to 30}ZPS; ZDD6.5, 7, 8F{from 7 to 20}Y; ZDD6.5, 7, 8F{from 7 to 20}PY; ZDD6.5, 7, 8F{from 7 to 20}ZY; ZDD6.5, 7, 8F{from 7 to 20}ZPY; ZDD9, 10F{from 10 to 20}Y; ZDD9, 10F{from 10 to 20}PY; ZDD9, 10F{from 10 to 20}ZY; 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ZDD6.5, 7, 8F{from 7 to 20}KLLI; ZDD6.5, 7, 8F{from 7 to 20}PKLLI; ZDD6.5, 7, 8F{from 7 to 20}ZKLLI; ZDD6.5, 7, 8F{from 7 to 20}ZPKLLI; ZDD9, 10F{from 10 to 20}KLLI; ZDD9, 10F{from 10 to 20}PKLLI; ZDD9, 10F{from 10 to 20}ZKLLI; ZDD9, 10F{from 10 to 20}ZPKLLI; ZDD11, 11.5, 12, 13F{from12 to 30}KLLI; ZDD11, 11.5, 12, 13F{from12 to 30}PKLLI; ZDD11, 11.5, 12, 13F{from12 to 30}ZKLLI; ZDD11, 11.5, 12, 13F{from12 to 30}ZPKLLI; ZDD6.5, 7, 8F{from 7 to 20}SR; ZDD6.5, 7, 8F{from 7 to 20}PSR; ZDD6.5, 7, 8F{from 7 to 20}ZSR; ZDD9, 10F{from 10 to 20}SR; ZDD9, 10F{from 10 to 20}PSR; ZDD9, 10F{from 10 to 20}ZSR; ZDD9, 10F{from 10 to 20}ZPSR; ZDD11, 11.5, 12, 13F{from12 to 30}SR; ZDD11, 11.5, 12, 13F{from12 to 30}PSR; ZDD11, 11.5, 12, 13F{from12 to 30}ZSR; ZDD11, 11.5, 12, 13F{from12 to 30}ZPSR; ZDT12F{from12 to 30}; ZDT12F{from12 to 30}P; ZDT12F{from12 to 30}Z; ZDT12F{from12 to 30}ZP; ZDT12F{from12 to 30}S; ZDT12F{from12 to 30}PS; ZDT12F{from12 to 30}ZS; ZDT12F{from12 to 30}ZPS; ZDT12F{from12 to 30}Y; 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KDJP8F{from 10 to 30}HKLLI; ZDJP8F{from 10 to 30}HKLLI; KDJP8F{from 10 to 30}HPKLLI; ZDJP8F{from 10 to 30}HPKLLI; KDJY8F{15, 18, 20}H; ZDJY8F{15, 18, 20}H; KDJY8F{15, 18, 20}HP; ZDJY8F{15, 18, 20}HP; KDJY8F{15, 18, 20}HS; ZDJY8F{15, 18, 20}HS; KDJY8F{15, 18, 20}HPS; ZDJY8F{15, 18, 20}HPS; KDJY8F{15, 18, 20}HY; ZDJY8F{15, 18, 20}HY; KDJY8F{15, 18, 20}HPY; ZDJY8F{15, 18, 20}HPY; KDJY8F{15, 18, 20}HSL; ZDJY8F{15, 18, 20}HSL; KDJY8F{15, 18, 20}HPSL; ZDJY8F{15, 18, 20}HPSL; KDJY8F{15, 18, 20}HKLLT; ZDJY8F{15, 18, 20}HKLLT; KDJY8F{15, 18, 20}HPKLLT; ZDJY8F{15, 18, 20}HPKLLT; KDJY8F{15, 18, 20}HKLLI; ZDJY8F{15, 18, 20}HKLLI; KDJY8F{15, 18, 20}HPKLLI; ZDJY8F{15, 18, 20}HPKLLI; KDJY8F{15, 18, 20}HSR; ZDJY8F{15, 18, 20}HSR; KDJY8F{15, 18, 20}HPSR; ZDJY8F{15, 18, 20}HPSR; KDD6.5, 7, 8F{from 7 to 20}H; KDD6.5, 7, 8F{from 7 to 20}HP; KDD6.5, 7, 8F{from 7 to 20}HZ; KDD6.5, 7, 8F{from 7 to 20}HZP; KDD9, 10F{from 10 to 20}H; KDD9, 10F{from 10 to 20}HP; KDD9, 10F{from 10 to 20}HZ; KDD9, 10F{from 10 to 20}HZP; KDD11, 11.5, 12, 13F{from12 to 30}H; KDD11, 11.5, 12, 13F{from12 to 30}HP; KDD11, 11.5, 12, 13F{from12 to 30}HZ; KDD11, 11.5, 12, 13F{from12 to 30}HZP; KDD6.5, 7, 8F{from 7 to 20}HS; KDD6.5, 7, 8F{from 7 to 20}HPS; KDD6.5, 7, 8F{from 7 to 20}HZS; KDD6.5, 7, 8F{from 7 to 20}HZPS; KDD9, 10F{from 10 to 20}HS; KDD9, 10F{from 10 to 20}HPS; KDD9, 10F{from 10 to 20}HZS; KDD9, 10F{from 10 to



[illegible]



ZDT12F{from12 to 30}HZPKLLI; ZDT12F{from12 to 30}HSR; ZDT12F{from12 to 30}HPSR; ZDT12F{from12 to 30}HZSR; ZDT12F{from12 to 30}HZPSR

of Class II a, rule 7 according to Annex IX of 93/42/EEC Directive

covered by the Technical Files rev. 08, dated 2015

prfromuct releasing documentation: Departmental Norm No 01/1993, edit 07, Technological Instructions No 141, 142, 143, 144 and Lot Reports No BA 141, BA 142, BA 143, BA 144 which is considered as a part of this declaration

meets the provisions of the directive 93/42/EEC which apply to them.

UMDNS Code: 15-022

**APPLIED HARMONIZED STANDARDS:**

EN 556-1:2001/AC:2006, EN 1041:2008/A1:2013, ISO 2859-1:1991/Adm1:2011, EN ISO 7864:1995, EN ISO 80369-7:2017, EN ISO 9626:1995/A1:2001, EN ISO 10555-1:2009, 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 11070: 2014, 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 15223-1:2012, EN 20594-1:1993/A1:1997, EN 62366-1:2015

Conformity assessment procedure: Annex II except section 4 of Council Directive 93/42/EEC

NOTIFIED BODY: TÜV Rheinland LGA Products GmbH  
Tillystraße 2  
90431 Nürnberg



Warsaw, December 04<sup>th</sup>, 2018

Emil Płowiecki

Chairman of Balton Sp. z o.o.

**BALTON** Sp. z o.o.  
**POLAND**  
00-496 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