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Declaration of Conformity

MANUFACTURER: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
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We declare under our sole responsibility that:

The Medical Devices: Ureteral catheters Nelaton type

Models: KMN3F, KMN4F, KMN5F, KMN6F, KMN7F, KMN8F, KMN3FO,
KMN4FO, KMN5FO, KMN6FO, KMN7FO, KMN8FO, KMN3F110,
KMN4F110, KMN5F110, KMN6F110, KMN7F110, KMN8F110,

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

covered by the Technical Files, rev. 01, dated 2013

product releasing documentation: Departmental Norm No 01/2001, ver. 05, Technological Instruction No 331 and Lot Report No BA 331 which is considered as a part of this declaration

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

UMDNS CODE: 10-767

APPLIED HARMONIZED STANDARDS:

EN 556-1:2001/AC:2006, EN 1041:2008/A1:2013, EN 1618:1997,
ISO 2859-1:1999/Amd1:2011, EN ISO 10993-1:2009/A: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 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 ISO 15223-1:2016, EN 62366-1:2015

Conformity assessment procedure: Annex V + AnnexVII of 93/42/EEC directive

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



Warsaw, November 12, 2018

Emil Płowiecki

Chairman of Balton Sp. z o.o.

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