

PCN Catheter with Needle	EC Declaration of Conformity	Document #	CT-ANX-05-04
		Revision	08
		Date	03-04-2024

Corporate Office & Operations Site:
Aster Medispro Private Limited

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Product Name
: PCN Catheter with Needle

Product Family	PCNN
Accessories	Needle, Needle Obturator, Straightener, Urine Bag Connector.
Model	Refer UR-01 Catheters- CT-ANX-03- Product code
Size (Fr)	08.5, 10.0, 12.0, 14.0, 16.0, 18.0
Catheter Length (Cm)	22,30
Needle Length (Cm)	26.0,34.5
Needle Sheath (Cm)	24.0,32.5
Product Color	Blue (B)
Product Material	Polyurethane, Polypropylene, Poly vinyl chloride, Acrylonitrile Butadiene Styrene & Stainless steel
Class	Ila
Rule#	7
UMDNS/ GMDN Code	10735

Conformity Assessment Route:

Annex II, Excluding Section 4 of Council Directive 93/42/EEC and its revised version

Declaration:

We declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC, all prior amendments and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.

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Standards Applied:

EN ISO 13485:2016+A11:2021, EN ISO 14971:2019, EN ISO 11737-1:2018/ A1:2021 ,EN ISO 11737-2:2020, EN ISO 11140-1:2014, EN 556-1:2001/AC:2006, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-6:2016,EN ISO 11135-2014+A1:2019, EN ISO 11138-2:2017, EN 1422:2014

ISO 11140-1:2014, ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-7:2008/AMD 1:2019, ISO 10993-10:2021,ISO 10993-11:2018, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-9:2022,ISO 11138-1:2017, BS EN 13868:2002, IEC 62366-1:2015/AMD 1:2020, ASTM F1980-07:2011, ASTM F88/F88M-15, ASTM F1140/F1140M-13
EN 1618:1997

**Proposed
Notified Body:**

MTIC Intercer S.r.l
Via G.Leopardi, 14
20123 – Milano (MI)
Italy

Notified Body number:
0068

(EC) Certificate(s):

Date of Certificate:

Place & Date of Issue:

Bangalore & 03-04-2024

**Signature:
(Name & Designation)**


(Manikandan Thachat-Director)