Declaration of Conformity

Manufacturer:	Continence Care ApS
Office address:	Islevdalvej 184, 2610 Roedovre, Denmark
Product name:	PVC catheter;
Type or size:	1) Tiemann; 08Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr & 20Fr
	2) Nelaton; 08Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr & 20Fr
	3) Female; 08Fr, 10Fr, 12Fr, 14Fr, 16Fr & 18Fr
	4) Rectal; 22Fr, 25Fr, 28Fr & 30Fr
GMDN Code:	10734
Classification (MDD Annex IX):	Class Is, Rule 5
Conformity Assessment Route:	MDD 93/42/EEC, Annex VII coupled with Annex V
Applicable directive:	Council Directive 93/42 EEC of 14th June 1993 concerning medical devices, amended by Directive 2007/47/EC of 5th September 2007.
Harmonized standard(s):	ISO 1618:1997, ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-11:2018, ISO 11135-1:2007, ISO 11138-2:2009, ISO 11607-1:2009, ISO 11607-2:2006, ISO 11737-1:2006, ISO 11737-2:2009, ISO 13485:2016, ISO 14971:2012, ISO 15223-1:2016, ISO 15986:2011, ISO 62366:2008, EN 556-1:2001 & EN 1041:2008.
Notified Body:	DNV Product Assurance, Veritasveien 3, 1363 Hoevik, Norway
Identification No.:	2460
Certificate Reg. No.:	10000380079-PA-NA-DNK – Rev 0.0
Certificate expiry date:	2022-03-27
Contact on technical documentation:	Flemming S. Andersen, Managing Director Islevdalvej 184, 2610 Roedovre, Denmark

We, the manufacturer, hereby declare that above mentioned products meet the transposition into national law as per the provisions of the EC Council Directive 93/42 EEC of 14th June 1993 amended by Directive 2007/47/EC of 5th September 2007.

Production period covered by this issued declaration: 1st January 2022 to 31st December 2022

Signed in Roedovre: 20th December 2021

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Name & position: Flemming S. Andersen, Managing Director
On behalf of: Continence Care ApS

Continence Care ApS
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