EU Declaration of Conformity
GentleCath Glide Hydrophilic Intermittent Urinary Catheter Technical Documentation
MDR CCCTF_006

This Declaration of Conformity is issued under the sole responsibility of ConvaTec Limited

We hereby declare that the mentioned product/attached list of products comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745

Legal Manufacturer:	ConvaTec Limited First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU, United Kingdom
SRN:	GB-MF-000001770
Authorized Representative:	Unomedical a/s Aaholmvej 1-3, Osted, 4320, Lejre, Denmark
Product Name:	GentleCath Glide Hydrophilic Intermittent Urinary Catheter
GMDN Code and Term Name:	45603: Single-administration urethral drainage catheter
EMDN Code and Term Description:	U0101: URETHRAL PROSTATIC AND BLADDER CATHETERS, WITHOUT BALLOON
CND Code and Title:	U0101: UROLOGICAL CATHETERS, NOT SELF-RETAINED
Basic UDI-DI:	768455CC0002VM
Identification of the device(s) concerned:	Refer to Appendix A
Catalogue Number:	Refer to Appendix A
Intended Purpose:	To provide an intermittent pathway for drainage of fluids from the urinary bladder. The catheter is inserted through the urethra.
Risk Classification:	Class I Sterile as per Rule 5 in Annex VIII
Conformity Assessment Route:	Annex IX of EU Medical Device Regulation (EU) 2017/745
Relevant Harmonised Standards:	EN ISO 15223-1:2021 — Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) EN ISO 11137-1:2015 — Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11737-1:2018 — Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-2:2020 — Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
References to any CS:	No common specifications have been used in relation to conformity
Identification of Notified Body:	BSI Group The Netherlands B.V. (BSI 2797)
Identification of the Certificate(s):	EU Quality Management System Certificate (Regulation (EU) 2017/745, Annex IX Chapter I and III). No. MDR 738968 R000 (ref 3586985). Issued by BSI (2022-01-26).

Identification of the Person authorized to sign on behalf of Legal Manufacturer:	**Signature:** DocuSigned by: Courtney Smith _____ **Date:** 2 JUN 2023 Courtney Smith – Senior Director, Regulatory Affairs Signer Name: Courtney Smith Signing Reason: I approve this document Signing Time: Jun 5, 2023 | 12:22:22 PM BST 18C584297FF34C80A5D3283D05D64343 Place of Issue: Deeside, Flintshire

Appendix A: List of Product Range Covered under this Declaration of Conformity

ICC	SAP EU	SAP US	Description
421564	1718753	1713710	GentleCath Glide Male CH08 (1x30pk)
421565	1718754	1713711	GentleCath Glide Male CH10 (1x30pk)
421566	1718756	1713713	GentleCath Glide Male CH12 (1x30pk)
421567	1718757	1713714	GentleCath Glide Male CH14 (1x30pk)
421568	1718758	1713715	GentleCath Glide Male CH16 (1x30pk)
421569	1718759	1713716	GentleCath Glide Male CH18 (1x30pk)
510480	1731956	1728295	GentleCath Glide Male CH08 (1x10PK)
510481	1731957	1728296	GentleCath Glide Male CH10 (1x10PK)
510482	1731958	1728297	GentleCath Glide Male CH12 (1x10PK)
510483	1731959	1728298	GentleCath Glide Male CH14 (1x10PK)
510484	1731960	1728299	GentleCath Glide Male CH16 (1x10PK)
510485	1731961	1728300	GentleCath Glide Male CH18 (1x10PK)
421570	1718760	1713717	GentleCath Gl Female CH08 (1x30pk)
421571	1718761	1713718	GentleCath Gl Glide Female CH10 (1x30pk)
421572	1718762	1713719	GentleCath Gl Female CH12 (1x30pk)
421573	1718763	1713720	GentleCath Gl Female CH14 (1x30pk)
421574	1718764	1713721	GentleCath Gl Female CH16 (1x30pk)
510475	1731951	1728301	GentleCath GL Female CH08 (1x10PK)

510476	1731952	1728302	GentleCath GL Female CH10 (1x10PK)
510477	1731953	1728303	GentleCath GL Female CH12 (1x10PK)
510478	1731954	1728304	GentleCath GL Female CH14 (1x10PK)
510479	1731955	1728305	GentleCath GL Female CH16 (1x10PK)
421907	1718768	1718774	GentleCath Tiemann CH08 (1x30pk)
421908	1718769	1718775	GentleCath Tiemann CH10 (1x30pk)
421909	1718770	1718776	GentleCath GL Glide Tiemann CH12 (1x30pk)
421910	1718771	1718777	GentleCath Tiemann CH14 (1x30pk)
421911	1718772	1718778	GentleCath Tiemann CH16 (1x30pk)
421912	1718773	1718779	GentleCath Tiemann CH18 (1x30pk)
510469	1731962	1728289	GentleCath Tiemann CH08 (1x10PK)
510470	1731963	1728290	GentleCath Tiemann CH10 (1x10PK)
510471	1731964	1728291	GentleCath Tiemann CH12 (1X10PK)
510472	1731965	1728292	GentleCath G Tiemann CH14 (1x10PK)
510473	1731966	1728293	GentleCath Thiemann CH16 (1x10PK)