Hillrom™

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:
European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Document Number 80017167	Version K	
Product Name	Connex Central Station (CS)	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
EC Certificates Declaration of Conformity Validity	EC Certificate 314505 MR2 Expiry Date: 2024-05-26	
EC REP and Importer	Welch Allyn Limited Navan Business Park, Dublin Road, Navan Co. Meath, C15 AW22, Ireland	SRN: IE-AR-000000768
REF #	106901 411066 107203 107205 107981 107985 108113 108114 108142 108143	
	901066 Monitoring Station	
Radio equipment	N/A	

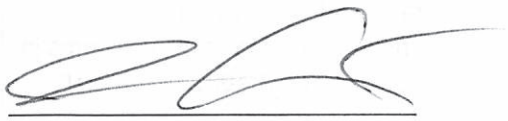
Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

Object of the declaration	 Connex Central Station (CS)
Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	IIb
Medical Device Classification Rule	Rule 10
Standards	See Appendix A
GMDN Code and Term	59378: Bedside physiologic monitoring software
UMDNS Code and Term	26708: Software, Physiologic Monitoring
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

Hillrom™

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

Authorised Signatory



Joshua Kim
Senior Manager
Global Regulatory Affairs

2022 · 01 · 13
Date

Skaneateles Falls NY, USA
Place of Issue

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
	EN 60601-1	2014	Medical electrical equipment_- Part_1: General requirements for basic safety and essential performance
	EN 60601-1-8	2017	Medical Electrical equipment - Part 1-8: General requirements for basic safety and essential performance- Collateral Standard: General Requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.
	EN 60601-2-49	2015	Medical electrical equipment_- Part_2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
	EN 62304	2015	Medical device software - Software life-cycle processes
	EN 62366-1	2015	Medical devices_- Application of usability engineering to medical devices
	EN ISO 15223-1	2016	Medical devices_- Symbols to be used with medical device labels, labelling and information to be supplied_- Part_1: General requirements