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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 J

Product Name Connex Central Station (CS)

Manufacturer's Name and Welch Allyn, Inc. SRN: None issued
Business Address 4341 State Street Road
 Skaneateles Falls, NY 13153
 USA

Declaration of Conformity EC Certificate 314505 MR2 Expiry Date: 2024-05-26
Validity

EC Certificates EC Certificate 314505 MR2


EC REP Welch Allyn Limited SRN: IE-AR-000000768
and Importer Navan Business Park, Dublin Road
 Navan Co. Meath
 C15 AW22 Ireland

REF	#	106901
		411066
		107053
		107203
		107205
		107981
		107985
		108113
		108114
		108142
		108143

901066 Monitoring Station

Radio equipment N/A

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Object of the declaration	 <p style="text-align: center;">Connex Central Station (CS)</p>
Accessories and components	See Appendix A
Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	IIb
Medical Device Classification Rule	Rule 10
Standards	See Appendix B
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



DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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

Authorised Signatory

A handwritten signature in black ink, appearing to be 'JK', written over a horizontal line.

Joshua Kim
Senior Manager
Global Regulatory Affairs

2021.09.13
Date

Skaneateles Falls NY, USA
Place of Issue



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Appendix A: Accessories and Components

SKU	Description
N/A	No Accessories

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Appendix B: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects. Good clinical practice
	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	2016	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 14971	2012	Medical devices_ - Application of risk management 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
	EN IEC 80001-1 section 3.5 2011	2011	Application of risk management for IT-networks incorporating medical devices_ - Part_1: Roles, responsibilities and activities.

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Document Change History

Version	Description	Author	Date
A	Initial release – Connex CS 1.1 Draft for DQS Review	Susan Schmidt	2013-01-31
B	Connex CS 1.1 (Connex Workstation) – signed version	Susan Schmidt	2013-09-17
C	Updated for Connex CS ES (1.5) – Draft for DQS review	Susan Schmidt	2013-09-25
D	Updated to add RoHS and update to latest template. No need for Annex for Saudi Arabia because RPI number is being used. This version corresponds to Connex CS version 1.6 or later.	Susan Schmidt	2014-07-11
E	Updated DoC for new Part numbers 106901, 105736, 411066. Version corresponds to CS 1.8. or later	Gary Brennan	2017-10-10
F	Updated DoC to add service kit material numbers: 107053, 107203, 107205, 107981, and 107985; updated to meet the requirements of the guidance document EK-MED 3.9 A4	Susan Schmidt	2019-12-13
G	Updated UMDNS number to software only code, addition of 108113 and 108114, addition of EN ISO 14971 and EN ISO 14155 standard	Chris Lefancheck	2019-12-18
H	Updated DoC to add material numbers	Scott Stearns	2020-05-21
J	Updated DoC to add material Numbers. Deleted Material Number CONNEX ENTERPRISE: PN is now at OB status. Updated Standards Table per ASL. Updated to new Hillrom Template	Mark Alsberge Kim Ockenfels	2021-09-08