
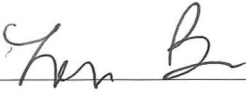


Document Number: 80017167 Version: G

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

| | |
|--|---|
| Product Name: | Connex Central Station (CS) |
| Manufacturer's Name and Address: | Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153 USA |
|  | Welch Allyn Limited Navan Business Park, Dublin Road, Navan, Co Meath, C15 AW22, Ireland |
| Notified Body: | DQS Medizinprodukte GmbH August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297 |
| Conformity Assessment Route: | Annex II |
| Part Numbers: | Refer to Appendix A for Part Numbers and their corresponding Class, Class Rule, GMDN Code, and UMDNS Code. |
| Standards: | Refer to Appendix B |
| Validity Limitation: | The declaration replaces the previous revision and applies to products produced after the date this document is approved. |



 Lori Burns
 Regulatory Affairs Dir QARA

2019/12/18

 Date

Skaneateles Falls, NY USA

 Place of Issue

Document Number: 80017167 **Version:** G

Appendix A: Part Numbers

| Device | | | |
|----------------------------|-------------------|---|--|
| Class: | IIb | | |
| Class Rule: | 10 | | |
| GMDN Code and Term: | 59378 | Bedside physiologic monitoring software | |
| UMDNS Code and Term | 26708 | Software, Physiologic Monitoring | |
| REF | # | Description | |
| 901066 | 106901 | CONNEX CSAS CONTINUOUS | |
| 901066 | 107053 | 1.7.1 CONNEX CENTRAL STATION SW | |
| 901066 | 107203 | CSAS 1.8 CONTINUOUS | |
| 901066 | 107205 | CONNEX CENTRAL STATION 1.8 SW ONLY | |
| 901066 | 107981 | CSAS 1.8.1 CONTINUOUS | |
| 901066 | 107985 | CONNEX CENTRAL STATION 1.8.1 SW ONLY | |
| 901066 | 108113 | CSAS 1.8.2 CONTINUOUS | |
| 901066 | 108114 | CONNEX CENTRAL STATION 1.8.2 SW ONLY | |
| 901066 | 411066 | CONNEX CENTRAL STATION SW ONLY | |
| 901066 | CONNEX ENTERPRISE | CONNEX ENTERPRISE | |

Document Number: 80017167 Version: G**Appendix B: Standards (and Common Specifications)**

| Number | Title |
|--------------------|---|
| EN 60601-1-8 | 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 | Medical Electrical Equipment - Part 2-49: Particular Requirements for the Basic Safety and Essential Performance of Multifunction Patient Monitoring Equipment |
| EN 62304 | Medical Device Software - Software Life-Cycle Processes |
| EN 62366-1 | Medical Devices - Part 1: Application of Usability Engineering to Medical Devices |
| EN 1041 | Information Supplied by the Manufacturer of Medical Devices |
| EN/ISO 15223-1 | Medical Devices - Symbols to be Used with medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements |
| ISO 7000 | Graphical symbols for use on equipment |
| IEC 60417 Database | Graphical symbols for use on equipment |
| EN ISO 14971 | Medical Devices - Application of Risk Management to Medical Devices |
| EN ISO 14155 | Clinical Investigation of Medical Devices for Human Subjects |