





CERTIFICATE

This is to certify that the company

Welch Allyn, Inc

4341 State Street Road Skaneateles Falls, NY, 13153 United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

Scope:

Design, development, manufacture, distribution, installation and service of finished medical devices, systems, lighting products and associated components and accessories for use in gastroenterological and gynaecological endoscopic procedures, cardiopulmonary assessment and intervention, acquiring and monitoring vital signs, monitoring systems and the examination and test of the eyes, ears, nose, throat, and skin.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07

EN ISO 13485 : 2016 + AC : 2016

ISO 13485: 2016

Certificate registration no. 314505 MP2016

Certificate unique ID 170716579

Effective date 2019-06-13

Expiry date 2019-12-08

Frankfurt am Main 2019-06-13



DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director

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Dr. Thomas Feldmann Head of Certification Body







Annex to certificate

Certificate registration No.: 314505 MP2016

Certificate unique ID: 170716579

Effective date: 2019-06-13

Welch Allyn, Inc

4341 State Street Road Skaneateles Falls, NY, 13153 United States of America

Location

468503 Welch Allyn, Inc.4341 State Street Road Skaneateles Falls, NY, 13153 United States of America

354834
Welch Allyn Beaverton
Development and Technology Center
9525 SW Gemini Dr.
Beaverton, OR, 97008
United States of America

Scope

Design, development, manufacture, distribution, installation and service of medical devices, systems, lighting products and associated components and accessories for use in gastroenterological and gynaecological endoscopic procedures, cardiopulmonary assessment and intervention, acquiring and monitoring vital signs, monitoring systems and the examination and test of the eyes, ears, nose, throat, and skin.

Design and development of wireless and software components for medical devices.

