

Welch Allyn Australia (Pty) Ltd. Unit 5, 38 – 46 South Street Rydalmere NSW 2116

## MANUFACTURER'S DECLARATION OF CONFORMITY AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002 DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.:

80021264

Version:

A

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:

Welch Allyn, Inc.

Business address:

4341 State Street Road

Skaneateles Falls, NY 13153-0220

U.S.A.

Product name:

Neonate Blood Pressure Hose

#

008-0265-02

Classification:

I

GMDN code and term:

14238 - Tubing

Scope of application:

All

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Standards applied:

IEC 80601-2-30

2009

Medical electrical equipment -- Part 2-30: Particular

requirements for basic safety and essential performance of automated non-invasive

sphygmomanometers

Authorised Signatory:

Tim Croft Sr. Manager, Regulatory Affairs - JAPAC Date

2016-02-03

Rydalmere, NSW

Place of Issue

This authorisation is given in the signatory's capacity as representative of the "Manufacturer" (as recorded on page 1 of this declaration)