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MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

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: ANSELL HEALTHCARE EUROPE N.V.

Business Address: Bld Internationalelaan 55,
B-1070 Brussels,
Belgium

Medical device(s): Microflex® TQ-601Soft White Nitrile Examination Gloves

Classification: Class I

GMDN Code and Term: 56286 - Nitrile examination/treatment glove, non-powdered, non-sterile

Scope of Application: All examination gloves from this manufacturer

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: EN 455 Parts 1, 2, 3, & 4 and ISO 11193-1

Authorized Signatory:

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Name: Samantha Marshall
Position: Associate Director Regulatory Affairs
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