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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 NV

Business Address: Boulevard International 55
Brussels, B-1070
Belgium

Medical device(s): Microflex® Neogard Touch 73-737

Classification: Class I

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

Scope of Application: All examination gloves from this manufacture

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: ASTM D6319 and ISO 11193-1

Authorized Signatory:

Ansell Healthcare Europe NV
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Position: Director Regulatory Affairs Medical EMEA / APAC
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