Ansell Healthcare Europe NV
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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):	Micro-Touch® DermaClean Sterile®
Classification:	Class I Sterile
GMDN Code and Term:	59096 Hevea-latex examination/treatment glove, non-powdered, sterile
Scope of Application:	All examination gloves from this manufacturer

Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules and these procedures.

Certificate Number for the Production Quality Assurance Procedures: EC Certificate No. CE 01537

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

Authorized Signatory:

Ansell Healthcare Europe NV
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Name: Samantha Marshall
Position: Associate Director Regulatory Affairs
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