

DECLARATION OF CONFORMITY

This declaration is made in accordance with the requirements of Annex VII of the Directive 93/42/EEC

Manufacturer: Ansell Healthcare Europe N.V.

Classification: Class IIa

GMDN Code & Definition: 47178 – Hevea-latex surgical glove, non-powdered, non-antimicrobial

Brand Names:

Brand	Size	External Reference Code	Market Regions
ENCORE® Latex Micro	5.5	330104055	EMEA/APAC
ENCORE® Latex Micro	6	330104060	EMEA/APAC
ENCORE® Latex Micro	6.5	330104065	EMEA/APAC
ENCORE® Latex Micro	7	330104070	EMEA/APAC
ENCORE® Latex Micro	7.5	330104075	EMEA/APAC
ENCORE® Latex Micro	8	330104080	EMEA/APAC
ENCORE® Latex Micro	8.5	330104085	EMEA/APAC
ENCORE® Latex Micro	9	330104090	EMEA/APAC
ENCORE® Latex Micro	5.5	5787000	NA/LAC/APAC
ENCORE® Latex Micro	6	5787001	NA/LAC/APAC
ENCORE® Latex Micro	6.5	5787002	NA/LAC/APAC
ENCORE® Latex Micro	7	5787003	NA/LAC/APAC
ENCORE® Latex Micro	7.5	5787004	NA/LAC/APAC
ENCORE® Latex Micro	8	5787005	NA/LAC/APAC
ENCORE® Latex Micro	8.5	5787006	NA/LAC/APAC
ENCORE® Latex Micro	9	5787007	NA/LAC/APAC
ENCORE® Latex Micro	5.5	5787000	INDIA
ENCORE® Latex Micro	6	5787001	INDIA
ENCORE® Latex Micro	6.5	5787002	INDIA
ENCORE® Latex Micro	7	5787003	INDIA
ENCORE® Latex Micro	7.5	5787004	INDIA
ENCORE® Latex Micro	8	5787005	INDIA
ENCORE® Latex Micro	8.5	5787006	INDIA
ENCORE® Latex Micro	9	5787007	INDIA

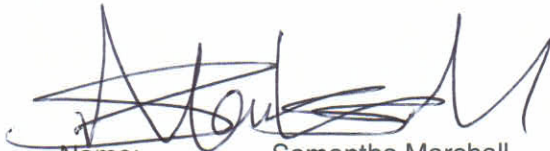
Brand	Size	External Reference Code	Market Regions
ENCORE® Latex Micro	6	330104060	BRAZIL
ENCORE® Latex Micro	6.5	330104065	BRAZIL
ENCORE® Latex Micro	7	330104070	BRAZIL
ENCORE® Latex Micro	7.5	330104075	BRAZIL
ENCORE® Latex Micro	8	330104080	BRAZIL
ENCORE® Latex Micro	8.5	330104085	BRAZIL

Conforms to the applicable essential requirements of Annex I of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47 /EEC

With production systems certified, where applicable, through the British Standards Institution, Notified Body Number 2797, Certificate Number CE 01537 under Annex V of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47/EEC.

Signed on behalf of the Manufacturer

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