Ansell Healthcare Europe NV/SA
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EU DECLARATION OF CONFORMITY

Manufacturer Name/Address: Ansell Healthcare Europe NV/SA
Riverside Business Park,
Block J, Boulevard International 55,
1070 Brussels,
Belgium

SRN Number: BE-MF-000000691

Risk Class: Class I

Intended Purpose: A non-sterile device intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanity purposes. The device is used mainly as a two-way barrier to protect both the patient and wearer against cross contamination. This is a single-use device.

EMDN Code and Description: T01020204 - Nitrile Examination/Treatment Glove

Basic UDI-DI: 5414566 MF93868 FE

Product Name(s):

Product Description	Size	Product Code	Region
Microflex® 93-868 LifeStar™ EC	S	93868070	EMEA
Microflex® 93-868 LifeStar™ EC	M	93868080	EMEA
Microflex® 93-868 LifeStar™ EC	L	93868090	EMEA
Microflex® 93-868 LifeStar™ EC	XL	93868100	EMEA
Microflex® 93-868 LifeStar™ EC	XXL	93868110	EMEA
Microflex® 93-868 LifeStar™ EC	3XL	93868120	EMEA
Microflex® 93-868 LifeStar™ EC	M-XL	93868000-SAMP	EMEA

Conformity Assessment Procedure: Annex I & Annex II + Annex III

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This EU Declaration of Conformity is issued under the sole responsibility of Ansell Healthcare Europe NV/SA.

We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signed on behalf of Ansell Healthcare Europe NV

Ansell Healthcare Europe NV
Riverside Business Park - Block J
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BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA / APAC
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