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 dedicated marker intended to be used to delineate areas on the skin surface of a patient utilizing non-toxic ink.

EMDN Code and Description: V9004 – Skin Marking Demographic Pencils and Pens

Basic UDI-DI: 5414566 SANSM10 YD

Product Name(s):

Product Name	Product Code	Market Region
Sandel® Petite Skin Marker™	1011-NNS	EMEA
Sandel® Petite Skin Marker™	1011-NS1	EMEA
Sandel® Skin Marker™, Bulk	1019-NNS	EMEA
Sandel® 2-in-1™ Marker, Bulk	1031-NNS	EMEA
Sandel® 2-in-1™ Marker with labels and ruler, bulk	1031-LRNS	EMEA
Sandel® 4-in-1™ Marker, Bulk	1041-NNS	EMEA
Sandel® 4-in-1™ Marker (No time out sleeve)	1041-NS1	EMEA
Sandel® 4-in-1™ Marker with labels and ruler	1041-LRNS	EMEA

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

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.

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Signed on behalf of Ansell Healthcare Europe NV

Ansell Healthcare Europe NV
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BELGIUM

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