

DECLARATION OF CONFORMITY

This UK Declaration of Conformity is issued under the sole responsibility of Ansell Healthcare Europe NV.

Manufacturer Name/Address: Ansell Healthcare Europe NV
Boulevard International 55,
Brussels,
B-1070,
Belgium

UK Responsible Person: Ansell (U.K.) Limited
Building C,
Willerby Hill Business Park,
Willerby, Hull
HU10 6FE
United Kingdom

Risk Class: Class I

GMDN Code & Definition: 61575 – Skin marker – Skin Marking Pen, Single-use

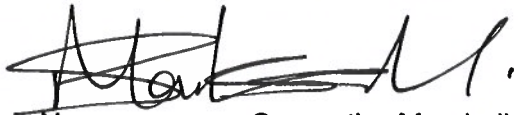
Product Name(s):

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

Conformity Assessment Procedure: Part II – Annex VII

We hereby declare that the medical device(s) specified above meet the provision of The Medical Devices Regulations 2002 (UK MDR 2002).

Signed on behalf of the Manufacturer



Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA / APAC
Date: 25 May 2023
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