



Declaration of Conformity

Notified Body Certified Product

Page 1 of 1

PRODUCT IDENTIFICATION

Catalog Number	Description
1019	SANDEL SKIN MARKER, STERILE
1019-R	SANDEL SKIN MARKER WITH RULER
1031	SANDEL 2-IN-1 MARKER, STERILE
1041	SANDEL 4-IN-1 MARKER, STERILE
1041-R	SANDEL 4-IN-1 MARKER W/RULER

Manufacturer	Ansell Sandel Medical Solutions LLC 9301 Oakdale Avenue, Suite 300 Chatsworth, CA 91311 USA
Authorized Representative	Emergo Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands
Notified Body	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany Notified Body ID: 0197

CONFORMITY ASSESSMENT

Certificate number	DD 60137247 001
Issue Date	March 11, 2019
Expiration Date	March 10, 2024
Device Classification	Class _Is_ Rule _1_
Route to Compliance	Annex _V_ of MDD 93/42/EEC
Standards (if applicable)	N/A

Ansell Sandel Medical Solutions LLC declares that the above mentioned product(s) is(are) in conformity with the provisions of Council Directive 93/42/EEC for Medical Devices. The Technical File has been filed and the Essential Requirements have been met as defined under Annex I. All supporting documentation are retained at ASMS in Chatsworth, California, USA

The undersigned hereby declares on behalf of Ansell Sandel Medical Solutions LLC that this declaration of conformity is issued under the sole responsibility of the manufacturer, Ansell Sandel Medical Solutions LLC.

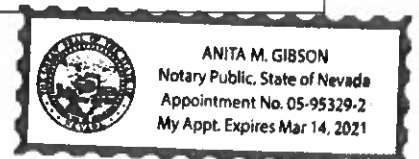
COMPANY REPRESENTATIVE

Title:	Quality Specialist
Printed Name:	Tena Jimmerson
Signature:	
Date:	07/31/2019
Location:	Chatsworth, CA – USA

State of Nevada County of Washoe

The foregoing instrument was acknowledged before me on this 31st day of July, 2019

By Notary Public. My Commission Expires March 14, 2021



CONFIDENTIAL