EC Declaration of Conformity

Manufacturers Name:	Van der Bend B.V.
Manufacturers Address:	Kloosterweg 34, 3232 LC Brielle (NL)
SRN (Single Registration Number):	NL-MF-000001575
Basic UDI-DI:	See product reference list
Name of the Device(s):	Van der Bend Patch Test Chambers
Classification:	I
Conformity assessment route:	The patch test chambers has been classified as Class I according to Annex VIII rule 1, and is in conformity with the general safety and performance requirements and provisions of the Regulation MDR 2017/745 and (are)(is) in conformity with the relevant harmonized standards: ISO 14971:2019 ISO 15223-1:2014 ISO 10993-5:2009 ISO 10993-10:2010 and is subject to the procedure set out in Annex II & III of the Regulation MDR 2017/745

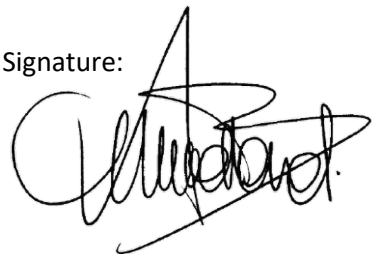
This declaration of conformity is issued under the sole responsibility of Van der Bend B.V.
We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

(Product reference list)

Name manufacturer	Productname	Article reference	BASIC-UDI (GTIN)	Classification
Van der Bend B.V.	Van der Bend Patch Test Chambers	4600	08717056720104	Class I (rule 1)

Signature:



Annemarie van der Bend
Director

Place and date of issue: Brielle, 18-05-2021

Van der Bend BV
Medical Supplies