

Declaration of Conformity

Product Identification

Product name: Prevantics CHG 2%
Brand name: PDI
Product Codes: XP00220, XP00314, ISW4040, ISW4050, XP00294
GMDN and term: 58077; medical device disinfection wipe
CE Cert: CE 628500

Manufacturer

Name: Professional Disposables International Ltd (PDI)
Address: Pywell Road
Willowbrook Industrial Estate
Corby
NN17 5XJ
Country: United Kingdom

European Authorised Representative

Name: Nex Medical Antiseptics Srl.
Address: Via Arluno, 37/39, 20010 Casorezzo Milan
Country: Italy

Notified Body

Name: BSI (British Standards Institute, (CE 2797)
Address: Say Building, John M Keynesplein 9, 1066 EP, Amsterdam.
Country: The Netherlands

Means of Conformity

PDI Ltd. declares that the product listed within the Technical File have been classified as Class **Ila** – Annex IX, Rule 15 and is in conformity with the Essential Requirements and provisions of Council Directive MDD 93/42/EEC. Conformity Assessment, Annex II.

Signature

Place and date: Corby 08/04/2022

Signature:



Name: Christopher Hill

Position: QA/RA & NPD Director






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Final Audit Report

2022-04-08

Created:	2022-04-08
By:	bethany dean (bethany.dean@pdi-emea.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAG8W_Q1WJSDYctH3DbE67tpvvkV122rzh

"DOC 07 Sani Coth CHG 2% (v7)" History

-  Document created by bethany dean (bethany.dean@pdi-emea.com)
2022-04-08 - 12:45:37 PM GMT
-  Document emailed to Chris Hill (christopher.hill@pdi-emea.com) for signature
2022-04-08 - 12:45:58 PM GMT
-  Email viewed by Chris Hill (christopher.hill@pdi-emea.com)
2022-04-08 - 3:08:11 PM GMT
-  Document e-signed by Chris Hill (christopher.hill@pdi-emea.com)
Signature Date: 2022-04-08 - 3:08:36 PM GMT - Time Source: server
-  Agreement completed.
2022-04-08 - 3:08:36 PM GMT