

Declaration of Conformity

Product Identification

Product name: Sani-Cloth Active
Brand name: PDI
EC Certificate
Reference: CE 628500
Product Codes: XP00190, XP00193, XP00188
GMDN and term: 58077; medical device disinfection wipe
CE Cert: CE 628500

Manufacturer

Name: Professional Disposables International Ltd (PDI)
Address: Aber Park, Flint. Flintshire
CH6 5EX
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: Flint, 22nd September 2020

Signature:



Name: Christopher Hill
Position: Quality, Regulatory and NPD Director