

## Declaration of Conformity

### Product Identification

Product name: Sani-Cloth AF  
Brand name: PDI  
Product Codes: XP00365, XP00366, XP00363, XP00390, XP00391, EAF1110,  
EAF1120, EAF1100, EAF1130, EAF1140, EAF1150  
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: Director, RA/QA/NPD






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Final Audit Report

2022-04-08

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