



**MEDICAL DEVICE TECHNICAL FILE APPENDIX  
MDR 2017/745**

**DECLARATION OF CONFORMITY**

**Manufacturer**

Name: Professional Disposable International Ltd (PDI)  
Address: Pywell Road, Willowbrook Industrial Estate, Corby, NN17 5XJ  
Country: United Kingdom  
Manufacturer SRN: GB-MF-000035214

**European Authorised Representative**

Name: Nex Medical Antiseptics Srl.  
Address: Via Per Arluno 37/39, 20003 Casorezzo, Milan  
Country: Italy  
EC REP SRN: IT-AR-000024938

**Product Identification**

Trade Name: PDI  
Product Name: Sani-Cloth® AF  
Product Codes: EAF1100, EAF1110, EAF1120, EAF1130, EAF1140  
Intended Use: Alcohol free, ready to use, low linting, disposable 2 in 1 cleaning and disinfection wipes for non-invasive medical devices; non-porous hard surfaces.  
EMDN and term: D0902, ASSOCIATED AMMONIUM SALTS FOR THE DISINFECTION OF MEDICAL DEVICES  
Basic UDI-DI: 50560123MDRTF02DN

**Notified Body**

Name: BSI (British Standards Institute, (CE 2797))  
Address: Say Building, John M Keynesplein 9, 1066 EP, Amsterdam  
Country: The Netherlands  
CE Certificate: 780250

**Means of Conformity**

PDI Ltd. declares that the product(s) listed within the Technical File have been classified as Class IIa - Annex VIII, Rule 16 and is in conformity with the General Safety and Performance Requirements and provisions of 2017/745 Medical Devices Regulation, Annex IX Chapter I and III. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

**Signature**

Place and date: Corby, 15/08/2024






Signature: 

Name: Christopher Hill

Position: Director, RA/QA/NPD

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|-----------------|--|
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