


EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Polyco Healthline Ltd	South Fen Road, Bourne, Lincolnshire, PE10 0DN. UK	GB-MF-000015289

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
International Associates Auditing & Certification Limited	The Black Church, St Mary's Place, Dublin 7, D07 P4AX Ireland	IE-AR-000002248	+353 16971561 EUAR@ie.ia-net.com

PRODUCT IDENTIFICATION		
Product Name	Code / Catalogue Number	Basic UDI-DI
Non-woven mask with Ties	DK01GT	5024951MMNS00RP
Intended Purpose	Photo	
Medical face masks to cover the nose and mouth and collect bodily fluid from the nose and mouth of the wearer preventing it contaminating the patient		

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		Common Specifications / Standards
Class:	I	BS EN 14683:2019 Type IIR
Rule:	1	

Polyco Healthline Ltd declares that the above-mentioned product meets the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: David Langridge

TITLE: Head of Technical

SIGNATURE: 

PLACE: Bourne, UK

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Head Office & Distribution Centres: South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK

www.polycohealthline.com Tel: +44 (0)33 3320 8550

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