

## 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 <a href="mailto:EUAR@ie.ia-net.com">EUAR@ie.ia-net.com</a>

PRODUCT IDENTIFICATION		
Product Name	Code / Catalogue Number	Basic UDI-DI
Non-woven mask with Loops	DK01BL	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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