





EU DECLARATION OF CONFORMITY


REVISION: 1.0

1	IDENTIFICATION OF THE LEGAL MANUFACTURER:		Azooza Ltd, Northside House, Mount Pleasant, Barnet, Herts UK EN4 9EE
	EC AUTHORISED REPRESENTATIVE	N/A	
<p align="center"><i>This EU declaration of conformity is issued under the sole responsibility of the manufacturer.</i></p>			
3	UNIQUE DEVICE IDENTIFIER (UDI):		Not available at this time
4	PRODUCT AND TRADE NAME	MEDICAL FACEMASK TYPE 1 BFE95%	
	PRODUCT CODE	VB68731	
	INTENDED PURPOSE	Medical face mask for general clinical and public use intended to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose. Not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements	
	IMAGES		
	LOT CODE	F102012	
5	RISK CLASS OF THE DEVICE IN ACCORDANCE WITH THE RULES SET OUT IN ANNEX VIII	CLASS I	
<p align="center"><i>The devices covered by this declaration are in conformity with the European Medical Devices Directive 93/42/eec as modified by 2007/47/EC</i></p>			
7	REFERENCES TO ANY CS USED AND IN RELATION TO WHICH CONFORMITY IS DECLARED	<p>EN14683:2019 Medical Face Masks – Requirements and Test Methods</p> <p>EN 1041:2008 Information supplied by the manufacturer of medical devices</p> <p>BS EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.</p>	
8	NAME AND IDENTIFICATION OF THE NOTIFIED BODY	N/R	



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9	DESCRIPTION OF THE ASSESSMENT PROCEDURE PERFORMED	Annex VI	
10	IDENTIFICATION OF THE CERTIFICATE(S) ISSUED	N/R	
11	ADDITIONAL INFORMATION		
12	IDENTIFICATION OF THE PERSON AUTHORIZED TO SIGN ON BEHALF OF THE MANUFACTURER	NAME: SIGNATURE: FUNCTION: PLACE OF ISSUE: DATE: Company Chop:	Myka Gallagher  QARA Director Welwyn, Hertfordshire 16/04/2020 <i>Azooza Ltd</i> <i>21 Oak Piece, Welwyn,</i> <i>Herts. AL6 0XE</i> <i>Tel: +44 1438 717116</i>