

GI UK Medical – Data sheet  
**Type IIR Surgical  
 Face Masks**



**Type IIR Medical Grade Surgical Face Mask (Non-Sterile)**


- Disposable Type IIR EN14683 Face Masks
- High Bacterial Filtration Efficiency (BFE) +99%
- Type IIR Fluid Repellent
- Protective 3 Layer Construction
- Single Use
- Ear Loop, Pleat Style Mask
- Non-Woven Breathable Fabric

Colour	Size	Type	Adjustable Nose Clips	Box Quantity	Product code
Blue	Universal (17cm x 9cm)	3-layer Ear Loop Mask	Yes	50	FM2R/2*



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European Commission

## Declaration of Conformity

**Manufacturer:** Hunan Wondo Medical Supplies Co., Ltd.  
**Address:** Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Technological Development Zone, Hunan, Province, China

**EU Authorised Representative:**  
 Osmunda Medical Technology Service GmbH  
 Address: Von Oppen-Weg 15, 14476 Potsdam, Germany  
 DIMDI code: DE/0000047267

**Device:** Medical surgical face mask  
**Model:** Flat form (ear loop and lexpert-up); Folded form  
**Classification (MDR, Annex VIII):** Class I  
**Conformity assessment route:** ANNEX II+ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following regulation (EU) MDR 2017/745. All supporting documentations are retained under the premises of the manufacturer.

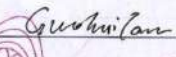
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**General applicable directives:**  
 Medical Device Directive: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

**Standard Applied:**

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

**Place, Date of Issue:**  
 Changsha, 30<sup>th</sup> March 2020

**Signature:**  
  
 Manager representative

