
CE DECLARATION

I, Rebecca Carbonnaux, of the The British Rototherm Company Ltd declare that the Type IIR Mask conforms to Regulation (EU) 2017/745.

The British Rototherm Company Ltd takes sole and full responsibility for this declaration. Technical documentation to validate this declaration will be available for 10 years from the last sale of foresaid device.

Product: **Type IIR Medical Mask**

Product Name: **IIR-MASK**

UDI (GTIN): **5060712790564**

Classification: **CLASS I Medical Device (Annex VIII (EU) 2017/745)**

Product Description:

The Roto Medical Type IIR Mask is a 3 layered material mask. The Type IIR Medical Mask is composed of a filter layer (melt blown) that is placed between 2 layers of fabric.

It is composed of 3 materials with a wire enclosed in the top of the material and elastic ear loops ultrasonically welded on.

There are pleats on the material to allow the user to expand the mask over the area from nose to chin.

Internal face is white, external face is blue.

Intended Use: **The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example, the noses and mouths of members of the surgical team. The main intended use of this medical mask is to protect the patient and/or medical professional from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids such as a patient's blood. This medical mask may also be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.**

Name and address of facility of design and manufacture of product:

**The British Rototherm Company Ltd
Kenfig Industrial Estate
Margam, Port Talbot
SA13 2PW
United Kingdom**

The object of declaration described above is in conformity with the European Union harmonised legislation stated below:

- **(EU) 2017/745**
- **EN 14683:2019**

The object of declaration described above is in conformity with the below technical specifications:

- **EN 14683:2019+AC:2019 Medical Face Masks – Requirements and test methods**
- **EN ISO 11737-1:2018 – Microbial Cleanliness (Bioburden)**
- **ISO 22609:2004 – Clothing for protection against infectious agents – Medical face Masks – Test method for resistance against penetration by synthetic blood**
- **EN 14683:2019 Annex C – Breathability (Differential Pressure)**

This declaration to conformance is made on behalf of The British Rototherm Company Ltd by:

Rebecca Carbonnaux

02/10/20

