



### EU Declaration of Conformity.

(This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer)

**Manufacturer:** WSR Medical Solutions Limited

**Authorised Representative:** Eurolink Europe Compliance Limited, Dublin D02 AY86

“The device(s) listed below and on the attachment fulfils the requirement of the Regulations of MDR (EU) 2017/745 which apply to the device.”


| Device name.                           | Basic UDI-DI  | Product code | Purpose of device  | Risk class. | SRN              |
|--|---------------|--------------|--|-------------|------------------|
| Type IIR Mask - A - MR Safe            | 5057326002732 | MRSIIR2A     | The purpose of surgical face masks is to filter out airborne particles which may contain biologically infected materials such as water or other fluid droplets and prevent them from passing from the user (clinician or medical worker) to the patient. – This product has been designed for safe use within MR scanners and has a <b>MR Safe Print</b> | Class 1     | GB-MF-0000117973 |
| Type IIR Mask - B - MR Safe – No Print | 5057326002749 | MRSIIR2B     | The purpose of surgical face masks is to filter out airborne particles which may contain biologically infected materials such as water or other fluid droplets and prevent them from passing from the user (clinician or medical worker) to the patient. – This product has been designed for safe use within MR scanners <b>NO MR Safe Print</b>        | Class 1     | GB-MF-0000117973 |

**RELEVANT HARMONISED STANDARDS:** EN 14683:2019; EN ISO 10993-5:2009

**GMDN:** 37713

**EMDN:** T020604 MEDICAL USE FACE MASKS, TYPE II AND IIR

RELEVANT COMMON SPECIFICATIONS:

ISSUED BY: NAME: Paul Dixon, SIGN:  DATE:.....MARCH 2022.....

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