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IREMA IRELAND(incorporating IREMA Thailand Co Ltd)

EU MDR DECLARATION OF CONFORMITY

This declaration is issued by and under the sole responsibility of JAHAN Co. t/a IREMA IRELAND (Incorporating IREMA Thailand Co Ltd), manufacturer of non sterile face-masks for the medical and dental industries, located at Kilmallock Business Park, Kilmallock, Co. Limerick V35 TF30, Ireland.

We hereby confirm that our products are in compliance with the applicable requirements for non sterile, Class 1 medical devices, as stipulated in the European Union Regulation Directive MDR EU 2017/745 ('the MDR').

All documents required under the MDR for Class 1 Medical Devices are available on site at Irema Ireland.

The Company is registered with our Competent Authority, the Health Products Regulatory Authority, as a manufacturer of Class 1, non-sterile, surgical and dental face masks; registration number IE/CA01/M/GM/0460. A EUDAMED SRN has not yet been issued.

Signed : _____ **Latest Signing Date : 14-04-21**

Andy Dawson
Quality & Regulatory Affairs Manager
Kilmallock

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SURGICAL & DENTAL FACE MASKS

Product Description:

The Irema range of face masks are categorized as Class 1 non sterile medical devices, primarily for use in surgical, general medical or dental applications where the primary intended use is to reduce the risk of infection of the patient and patient environment, and are sold into these markets under the brand name, 'Facemate'. Surgical masks are not intended to provide any form of respiratory protection for the wearer. The **Basic UDI-DI** associated with this product is **539153673001E2**.

Those masks specifically intended for use in potential medical respiratory applications, such as TB, laser surgery etc, are registered under our PPE certification and are thus classed as respirator masks, not medical devices, under separate EU Declaration cover.

The 'Facemate' flat mask is a multi-layer rectangular mask with three overlapping pleats and either 4 tie tapes or 2 elastic loops. The top edge of the mask is bound with either a highly absorbent air-laid towelling or 100% PP which encapsulates a pliable nosepiece. The remaining three sides are edged with a polypropylene material. The inner cover stock consists of white smooth surfaced polypropylene. The outer cover stock can be plain or printed wet-laid non-woven material, or 100% polypropylene. Sandwiched between the two cover stocks is a 100% polypropylene micro filter and optional non woven, 100% polypropylene layer for enhanced blood splash protection.

The performance of the surgical masks conforms to the relevant categories of the following standard at its current issue status:

EN 14683 Surgical masks – requirements and test methods

This is verified by suitably accredited external laboratories.

Material biocompatibility is controlled by selection of raw materials that have been tested by the manufacturer and meet required standards, and independent laboratory testing.

VARIANTS:

A range of masks are produced to Irema specifications and controlled by a series of product specification documents, PDN13. These documents are individually revision controlled under an index that is maintained by date of issue.