

**IREMA IRELAND(incorporating IREMA Thailand Co Ltd)**

**EC DECLARATION OF CONFORMITY**

JAHAN Co. t/a IREMA IRELAND (Incorporating IREMA Thailand Co Ltd), manufacturer of non sterile face-masks for the medical and dental industries, confirm that our products are in compliance with the applicable requirements for non sterile, Class 1 medical devices, including Annex VII as stipulated in the European Communities Directive 93/42/EE amended by Directive 2007/47/EC, and Irish Law SI 252 of 1994 (Medical Devices).

All documents required under CE Marking Directive 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.

Signed :



Andy Dawson  
Quality & Regulatory Affairs Manager

Revised Signing Date : 11-05-16



## 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 prevent infection of the patient and patient environment, and are sold into these markets under the Brand name, 'Facemate'. These surgical masks are NOT intended to provide any form of respiratory protection for the wearer.

Those masks specifically intended for use in potential medical respiratory applications, such as TB, laser surgery etc, are registered under our PPED certification and are thus classed as respirator masks, not medical devices, under separate EC 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 wed-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 blood splash enhancement. An integral anti-fog visor option is also available on the blood splash variants. The hi-performance version is a duck billed shape, 3 layer polypropylene mask with polyester binding and urethane elastic head loops.

The applicable\* surgical masks performance conform to the relevant categories of the following standard at its current issue status:

### EN 14683 Surgical masks – requirements and test methods

Verified by Nelson Laboratories, 6280 South Redwood Road, Salt Lake City, Utah, USA.

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.

