

Date: 01/06/2025

EU DECLARATION OF CONFORMITY

Manufacturer: Amray Medical
Manufacturers address: Unit 9, Greenhills Industrial Village
Drogheda, CO. Louth, Ireland

Notified body: SGS FIMKO OY, Notified body 0598
P.O.Box 30 (Särkiniementie 3), 00211 Helsinki, Finland

Object of Declaration:

- Semi-Wrap apron (Model 01),
- Semi wrap max apron (model 01S),
- Full wrap apron (model 01F),
- Single Front Apron Models A,B,C and Classic (Models 07 & 09),
- Theatre Drop Off Apron (Model 08),
- Double Sided Apron (Model 05),
- Vest & Skirt (Models 03,31,31S,44,45,46,47,48,49, 04 & 04NM),
- Coat Apron (Model 06),
- Backsaver (Model 02),
- Maternity Apron (Model 12),
- Urology Apron (Model 13)
- Orthopantomogram (Model 11),
- Dental (Model 10),
- Thyroid Collar (A, B-8cm & B-12cm), C, D, Cosy Collar,
- Backshield, Hand Protector, Epaulette, Shin Protector, Arm Protector, Foot Protector, Lead cap,
- Gonad Protector,
- Breast Protector,
- Ovarian Shield

Light aprons – Light Plus– Supreme Lead Free aprons with uniform nominal attenuation equivalence of 0.25mm, 0.35mm, 0.5mm and 1mmPb.

Classification: Category III

We declare that:

The factory production of the above with CE mark of products are subject to the conformity to type based on quality assurance of the production process (Module D), and EU type certificate (Module B) no. 0598/PPE/22/3863, 0598/PPE/22/3864 and 0598/PPE/22/2551 under surveillance of the notified body SGS FIMKO OY, Notified body 0598. The production is in conformity with the applicable requirements of Regulation (EU) 2016/425 and manufacturer's specifications based on EN 61331-3:2014 and testing under EN 61331-1:2014 plus guidance notes.

Instruction

We follow the instruction: PPE instruction: EU Regulation 2016/425 involved in personal protective equipment instruction.

Signed for and on behalf of:

Drogheda, 01/06/2025



William Johnston / Managing Director

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