EC Declaration of Conformity

Manufacturer:
MIP Inc.
9100 Ray Lawson Blvd.
Montréal (Anjou), Québec
H1J 1K8
Canada

Whose single authorized EU-Representative:
MIP Inc.
Rda. Sant Pere, 19-21 àtic 1a
08010 Barcelona
Spain
TVA-VAT: ESN4041211F

The undersgined Tor Lukenda Lund as Legal Representative of the Manufacturer (MIP Inc.)

Declares under its own responsibility that the device:

Reusable gown

Model: EHX4200-WAC

Classified according to Annex VIII of Regulation (EU) 2017/745 as:

CLASS I MEDICAL DEVICE (non sterile and without measuring functions)

Built according to the standards:

- UNI EN ISO 14971:2019: Medical devices - Application of risk management to medical devices;
- UNI EN ISO 1041:2009: Information provided by the Manufacturer with medical devices;UNI EN ISO 15233-1:2017: Symbols for use with labels, tags and information on the medical devices to be supplied - Part 1: General requirements;
- Regolamento (UE) n.1007/2011: Regulation relating to the names of textile fibers and to the labeling and marking of the fibrous composition of textile products;

Meets the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745.

The Technical File is kept at the following address:
9100 Ray Lawson Blvd. - Montréal (Anjou), Québec - H1J 1K8 - Canada

Montréal (Anjou), 2020.06.25

Signature: