



Operating Theatre Medical (Zhijiang) Co., Ltd.
欧格医疗用品（枝江）有限公司

Factory: Small & Medium Enterprises Industrial Park, Dongshi Town, Zhijiang City, 443200 Hubei, P.R.China.
Office: Room No.1101, Licheng Commercial Centre, No. 30, Jianmei Street. Jiangnan District, 430015 Wuhan, P.R.China



EU-DECLARATION OF CONFORMITY

in accordance with the EU Regulation 2016/425 on personal protective equipment
in accordance with the EU Regulation 2017/745 on medical devices

We, Operating Theatre Medical (Zhijiang) Co. Ltd,

With European Representative Mono-Use NV, Driesstraat 30, 8790 Waregem, Belgium
Tel + 32 56 60 81 51

herewith declare that the following PPE & MD device;

Product name	Isolation gown PPPE 40 Plus and PPPE 40 Plus Surge
Definition	Isolation gown is a gown worn by intended user to protect against exposure to chemicals and to minimize infective agents between medical staff and patient each other.
Description	A gown, with round collar, adjustable opening at back with lace at waist, with knitted cuff, is made of nonwoven fabric materials intended to be worn by healthcare providers to isolate themselves from chemical and patients. The isolation gown helps to protect the patient (e.g., burn patients) from the transfer of infectious agents carried by the healthcare provider; or it may help to protect the healthcare provider from a contagious agent which has infected the patient; or it may help to protect the intended user from chemicals. This is a single-use garment.
Intended purpose	Isolation gowns are used to minimize the transmission of infective agents or minimize the contact with cleaning materials of weak action or prolonged contact with water between medical staffs during checking and other non-invasive procedures, through prevention of dispersal of bacteria-carrying skin scales from medical staff to patient each other, and penetration of chemical or body fluids to the medical staff, thereby helping to prevent infections during checking and other non-invasive procedures.
EMDN code	T0205
Risk categories of PPE	Category III PPE device according the Annex I of the PPE Regulation (EU) 2016/425
Classification of MD	Class I medical device according Annex VIII, chapter III, rule 1 of the medical device Regulation (EU) 2017/745
Version	Non-sterile, single use product
Colour	Blue/yellow
Basic UDI -DI	6976128075000B3
Article	Isolation gown PPPE 40 Plus and PPPE 40 Plus Surge, blue and yellow,
OTM Item	Isolation gown PPPE 40 Plus - full & half laminated - blue color - S – XXXL Isolation gown PPPE 40 Plus - full & half laminated - yellow color - S - XXXL Isolation gown PPPE 40 Plus Surge - blue color - S – XXXL Isolation gown PPPE 40 Plus Surge - yellow color - S – XXXL

Complies with the requirements of the Regulation (EU) 2016/425 (Off. Journal of the EU L 81/31.03.2016) for personal protective equipment of category III and the harmonized standards (Off. Journal of the EU C209/15.06.2018) and complies with the relevant provisions of the EU Regulation 2017/745 as a class I medical device.



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Applicable Regulation	Regulation 2016/425 on personal protective equipment Regulation 2017/745 on medical devices
Applied harmonized standards	EN ISO 13688:2013+A1:2021, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009 and EN 14126:2003+AC:2004
Other relevant standards	EN 14325:2004



CE 0624

The protective clothing is identical to the PPE, which is the object of the EU- type examination procedure with certificate no. CE1084220007-00-02, (acc. to Module B), issued by the notified body 0624.
Notified Body 0624: Centro Tessile Cottoniero e Abbigliamento S.p.A.
Piazza S. Anna, 2 – 21052 Busto Arsizio (VA) – Italia.

In addition, the PPE is subject to the conformity assessment procedure acc. to Module C2, Annex VII of Regulation (EU) 2016/425 under supervision of the notified body Centro Tessile Cottoniero e Abbigliamento S.p.A. (0624)

Wuhan China 2026-04-27

Place, date

EC Declaration of Conformity
DOC no. OTM ECD_P03001 Rev 1.2

Mrs Sherry Liu
General Manager
Legally binding signature, function

