3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2026-MDR/QS-038

The Egyptian Italian Company

Plot 410 Industrial Zone, 800 Acres, Badr City - Cairo, 11829, Egypt
SRN No.: EG-MF-000040719
EUCEREP B.V.
Roald Dahllaan 33, 5629MC, Eindhoven, Netherlands

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Surgical Gown
Trade name: ATM Gown
Variants: see Annex I
Intended purpose: see Annex II
MD class Is
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

For class Is devices, the audit by the NB 2265 of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the Audit Report No. SK-0789/26 from 2026-05-10. Information on all examinations and tests performed is stated in the abovementioned report and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: 2026-06-17
Valid until: 2031-06-17
First issue: 2026-06-17
Revision: **00**
History: **see Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-06-17

©Tlačiareň cenín KASICO, a. s. Bratislava, KC26-00087

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-038

issued for the company

The Egyptian Italian Company

Plot 410 Industrial Zone, 800 Acres, Badr City - Cairo, 11829, Egypt

List of medical devices covered by the EU Quality Management System Certificate:

Basic UDI-DI:6223018073

Product name	REF number	Size	UDI-DI number
Standard gown small	GS01	S	6223018073284
Standard gown medium	GS02	M	6223018073291
Standard gown large	GS05	L	6223018073307
Standard gown X-large	GS03	XL	6223018073314
Standard gown 2 X-large	GS06	2XL	6223018073321
Standard gown 3 X-large	GS04	3XL	6223018073338
Reinforced gown small	GR01	S	6223018073345
Reinforced gown medium	GR02	M	6223018073352
Reinforced gown large	GR05	L	6223018073369
Reinforced gown X-large	GR03	XL	6223018073376
Reinforced gown 2 X-large	GR06	2XL	6223018073383
Reinforced gown 3 X-large	GR04	3XL	6223018073390
Full Reinforced gown small	GF01	S	6223018073406
Full Reinforced gown medium	GF02	M	6223018073413
Full Reinforced gown large	GF05	L	6223018073420
Full Reinforced gown X-large	GF03	XL	6223018073437
Full Reinforced gown 2 X-large	GF06	2XL	6223018073444
Full Reinforced gown 3 X-large	GF04	3XL	6223018073451

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA



Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-06-17
Valid until 2031-06-17

©Tlačiareň cenín KASICO, a. s. Bratislava, KC26-00087

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-038

issued for the company

The Egyptian Italian Company

Plot 410 Industrial Zone, 800 Acres, Badr City - Cairo, 11829, Egypt

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

A Medical device made of synthetic materials which is used during surgical procedures to help in protecting both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA



Katarina Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-06-17
Valid until 2031-06-17

©Tlačiareň cenín KASICO, a. s. Bratislava, KC26-00067

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-038

issued for the company

The Egyptian Italian Company

Plot 410 Industrial Zone, 800 Acres, Badr City - Cairo, 11829, Egypt

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2026-MDR/QS-038	2026-06-17	MDR508_2024	Initially issued certificate

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-06-17
Valid until 2031-06-17

©Tlačiareň cenín KASICO, a. s. Bratislava, KC25-00087