

Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

SC Coramed Medizinische Produkte SRL

Headquarters: **Str. Gladitei, Nr. 42, BL T6, ET.20, Ap. 2001, Sector 4, Bucarest, Romania**

Manufacturing plant: **Str. Unirii, Nr. 5-7, Calan, Jud. Hunedoara, Romania**

Scope:

Sterile surgery sets, sterile materials and devices used for surgical protection

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 124-CE-200625

Issue: 1
Issued: 21 December 2020
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Start date of certified status: 25 November 2015
Last certification cycle expiry date:
24 November 2020
Date of recertification audit:
30 November -1 December 2020
Expires:
25 May 2024

CE Certiso

Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager



The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
OP – Drapes (Campuri chirurgicale)	sterile, disposable OP Drapes	In surgical applications in the outpatient and inpatient sectors. The following areas should be addressed: General surgery, Anesthesia, Dental surgery, Endoscopy, Vascular surgery, Gynecology, Hand surgery, Otolaryngology, Intern medicine, Cardiology, Nephroscopy, Neurosurgery, Ophtalmology, Orthopedics, Plastic surgery, Radiology, Thoracic surgery, Traumatology and Urology.	OP Drapes OP Drapes, self-adhesive OP Drapes, with holes OP Drapes, with holes, self-adhesive, variable OP Drapes, with holes, self-adhesive, transparent edge, coated OP Drapes, with holes, rubber sleeve, velcro fastener OP Drapes, stockinett	Is / 1.
OP Gowns (Halate Chirurgicale)	sterile, disposable OP Gowns	In surgical applications in the outpatient and inpatient sectors. The following areas should be addressed: General surgery, Anesthesia, Dental surgery, Endoscopy, Vascular surgery, Gynecology, Hand surgery, Otolaryngology, Internaql medicine, Cardiology, Nephroscopy, Neurosurgery, Ophtalmology, Orthopedics, Plastic surgery, Radiology, Thoracic surgery, Traumatology and Urology.	OP Standard Gowns OP Reinforced Gowns	Is / 1.

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Description of the device	Type	Intended use	Model	Risk class
Equipment covers (Huse protectie aparatura)	sterile, disposable equipment covers	In surgical applications in the outpatient and inpatient sectors. The following areas should be addressed: General surgery, Anesthesia, Dental surgery, Endoscopy, Vascular surgery, Gynecology, Hand surgery, Otolaryngology, Internaq medicine, Cardiology, Nephroscopy, Neurosurgery, Ophtalmology, Orthopedics, Plastic surgery, Radiology, Thoracic surgery, Traumatology and Urology.	Standard Equipment covers Reinforced Equipment covers	I s / 1.
Surgical Sets (Seturi Chirurgicale)	sterile, disposable Surgical Sets	In surgical applications in the outpatient and inpatient sectors. The following areas should be addressed: General surgery, Anesthesia, Dental surgery, Endoscopy, Vascular surgery, Gynecology, Hand surgery, Otolaryngology, Internaq medicine, Cardiology, Nephroscopy, Neurosurgery, Ophtalmology, Orthopedics, Plastic surgery, Radiology, Thoracic surgery, Traumatology and Urology.	Surgical Sets (incl. Equipments Cover, Gowns, Drapes), Tapes, Waste Bags	I s / 1.

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