

Capitale Sociale € 11.000.000,00 I.V. - Trib. di Roma n. 1819/76
C.C.I.A.A. di Roma n.406417 – Codice Fiscale n. 02176330583
Partita Iva n. 01035041001

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Copag S.p.A.
Manufacturer address and contact details	Registered office - Operational headquarters Via Lucrezio Caro 63 00193 Roma - ITALY E-mail: info@copag.it Phone Number: +3906367371
Single Registration Number (SRN) (if available)	IT-MF-000015995

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

Notified body name (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	<input checked="" type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule its substitute(s) and signed written agreement(s) is be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Copag S.p.a.

Roma, 23/04/2024

Presidente
Dr. Marco Miraglia



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Schedule of Devices

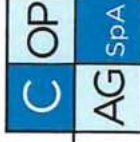
The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Garza pretagliata in puro cotone - in pacchi da kg 1 <i>Cotton Cut gauze – Pack 1 kg</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Tamponi rotondi con elastico RX- <i>Gauzes balls, with blue XRay threads</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Compresse di garza idrofila in cotone piegata e ribordata con filo di bario <i>Gauzes sponges with XRay threads</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



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PER GLI ACQUISTI E LE GESTIONI – SOCIETÀ PER AZIONI

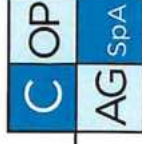


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Compresse di garza idrofila in cotone piegata e ribordata senza filo di bario <i>Gauzes sponges without XRay threads</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Compresse in TNT piegate senza filo di bario <i>Non woven swabs, without XRay threads</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Compresse laparatomiche con filo di bario <i>Laparatomy sponges with XRay threads</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Compresse di Garza in busta singola <i>Sterile gauze sponges in single envelope</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Compresse di Garza in busta doppia con etichetta removibile <i>Sterile gauze sponges in double envelope w/double control label</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Laparatomiche di Garza in busta singola senza filo di bario <i>Laparatomy sponges in single envelope without XRay</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA



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Laparotomiche di Garza in busta doppia con etichetta removibile <i>Laparotomy sponges in double envelope w/double control label</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Garza sterile in compresse <i>Sterile Gauzes sponges</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Cerotti e medicazioni sterili <i>Patches and medications in tnt</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Camici e copritelecamera sterili <i>Sterile surgical gown and sterile cover</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Telini da incisione non iodate <i>Sterile Surgical Drapes</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Defussori <i>Infusion set</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA
Sacche Urina <i>Sterile Urine bags</i>	0425-MED-003904-00	26/05/2024	ICIM S.p.a. - 0425	ICIM S.p.a. - 0425	31/12/2028	NA

