

## EC Declaration of Conformity

(Directive 93/42/EEC; R.D.1591/2009 regulating Medical Devices, Annex VII point 5 and Annex V point 3)

Mr. Ramón Lorente Royo, in his capacity as Managing Director of CARDIVAIS, S.A., with registered offices in the Parque Tecnológico de Andalucía, C/ Severo Ochoa nº64, C.P.: 29590, Campanillas (Málaga), manufacturer of the devices referred:

### DECLARES

That devices included in annex manufactured by Cardivais with **coverline®** brand are classified as a Class I (sterile) Medical Devices and that their manufacture and design comply with the provisions applicable in **Directive 93/42/EEC; R.D. 1591/2009 regulating Medical Devices, Annex VII point 5 and Annex V point 3**, and provides each and every performance ascribed to it.

**APPLICABLE STANDARDS:** UNE-EN ISO 11135, UNE-EN 868, UNE-EN 980, UNE-EN ISO 14971. UNE-EN ISO 13795. UNE-EN ISO 11737

That the organisation will keep the corresponding technical documentation up to date and meet the obligations stated in said Directives. It will likewise set up and maintain up to date a systematic procedure to review the experience gained, employing suitable means to apply corrective measures as necessary and inform the authorities.

That, by virtue of the above, the devices referred to in this declaration conforms to the provisions of Directive 93/42/EEC in compliance with current standards regulating medical devices and has the CE marking granted by Notified Body 0318, certificate number: 99 02 0206 CP.



March 2021

Ramón Lorente Royo

Managing Director

## ANNEX

Surgical drape (L) 50cm x 50cm	16100200
Surgical drape without adhesive (IS) 50cm x 50cm	16100202
Surgical drape without adhesive 3-layers 50cm x 50cm	16100204
Surgical drape (TP) 50cm x 50cm	16100205
Surgical drape without adhesive (IS) 50cm x 60cm	16100302
Surgical drape (L) 50cm x 75cm	16100400
Surgical drape without adhesive (IS) 50cm x 75cm	16100402
Surgical drape without adhesive 3-layers 50cm x 75cm	16100404
Surgical drape (TP) 50cm x 75cm	16100405
Surgical drape without adhesive (IS) 75cm x 90cm	16100602
Surgical drape without adhesive 3-layers 75cm x 90cm	16100604
Surgical drape (TP) 75cm x 90cm	16100605
Surgical drape without adhesive (IS) 75cm x 100cm	16100702
Surgical drape without adhesive (IS) 100cm x 100cm	16101102
Surgical drape without adhesive (TP) 100x100cm	16101105
Surgical drapes 100 x 150 cm (L)	16101200
Surgical drape without adhesive (PE) 100cm x 150cm	16101201
Surgical drape without adhesive (IS) 100cm x 150cm	16101202
Surgical drape without adhesive 3-layers 100cm x 150cm	16101204
Surgical drapes (TP) 100cm x 150cm	16101205
Surgical drape without adhesive (IS) 100cm x 200cm	16101302
Surgical drape without adhesive 3-layers 100cm x 180cm	16101404
Surgical drape without adhesive (IS) 150cm x 200cm	16101502
Surgical drape without adhesive 3-layers 150cm x 200cm	16101504
Surgical drape without adhesive (IS) 150cm x 240cm	16101602
Surgical drape without adhesive 3-layers 150cm x 240cm	16101604
Surgical drape without adhesive (IS) 175cm x 175cm	16102002
Surgical drapes (IS) 75cm x 75cm	16103102
Surgical drape without adhesive (IS) 90cm x 90cm	16103202
Surgical drape without adhesive (IS) 150cm x 150cm	16103502
Surgical drape with adhesive (IS) 50cm x 50cm	16105102
Surgical drape with adhesive 3-layers 50cm x 50cm	16105104
Surgical drape with adhesive (IS) 50cm x 75cm	16105202



Adhesive surgical drape (IS) 75cm x 75cm	16105302
Adhesive surgical drape (IS) 75cm x 75cm (adh.2,5cm)	16105302
Adhesive surgical drape 3-layers 75cm x 75cm	16105304
Surgical drape with adhesive 3-layers 75cm x 90cm	16105402
<i>Surgical drape with adhesive (IS) 75cm x 90cm (adh.2,5cm)</i>	16105412
Surgical drape with adhesive (IS) 100cm x 150cm	16105602
Surgical drape with adhesive 3-layers 100cm x 150cm	16105604
Adhesive surgical Sheet 180x150cm	16105702
Adhesive surgical sheet (IS) 240 x 150cm	16105802
Adhesive surgical sheets 3-layers 240cm x 150cm	16105804
Adhesive surgical sheet (IS) 240 x 150cm (adh.2,5cm)	16105812
Adhesive surgical sheets reinforced (IS) 240x150cm (adh.2,5cm)	16105832
Adhesive surgical sheets reinforced (IS) 240x150cm	16105892
Adhesive surgical sheets reinforced 3-layers 240cm x 150cm	16105894
Adhesive surgical sheets (IS) 175cm x 175cm	16105902
Adhesive surgical sheets 3-layers 175cm x 175cm	16105904
Adhesive surgical sheets (IS) 175cm x 175cm (adh.2,5cm)	16105912
Adhesive surgical sheets reinforced (IS) 175cm x 175cm (adh.2,5cm)	16105932
Adhesive surgical sheets reinforced (IS) 175x175cm	16105992
Adhesive surgical sheets reinforced 3-layers 175x175cm	16105994
Adhesive surgical drape (IS) 90cm x 75cm	16106202
Adhesive surgical drape 3-layers 90cm x 75cm	16106204
Adhesive surgical drape reinforced (IS) 90cm x 75cm (adh.2,5cm)	16106232
Adhesive surgical drape reinforced (IS) 90cm x 75cm	16106292
Adhesive surgical drape reinforced 3-layers 90cm x 75cm	16106294
Adhesive surgical drape (IS) 90cm x 90cm	16106302
Adhesive surgical drape 3-layers 90cm x 90cm	16106304
Adhesive surgical drape reinforced (IS) 90cm x 90cm	16106392
Adhesive surgical sheets (IS) 300cm x 175cm	16106402
Adhesive surgical sheets 3-layers 300cm x 175cm	16106404
Adhesive surgical sheets reinforced (IS) 300cm x 175cm (reinf.120x60cm)	16106410
Adhesive surgical sheets reinforced (IS) 300cm x 175cm (adh.2,5cm)	16106411
Adhesive surgical drape reinforced (IS) 100cm x 100cm	16106592
Adhesive surgical sheet (IS) 240cm x 175cm	16106602
Adhesive surgical drape reinforced (IS) 100cm x 90cm	16106792



Adhesive surgical drape reinforced (IS) 120cm x 100cm	16106807
Adhesive surgical sheet (IS) 150x150cm	16106906
Adhesive surgical sheets reinforced (IS) 175cm x 300cm	16106913
Adhesive surgical sheet (IS) 150x100cm	16106915
Adhesive surgical drape reinforced (IS) 190cm x 175cm	16106917
Adhesive surgical sheets (IS) 200 x 150cm	16106920
Adhesive surgical sheets (IS) 150cm x 240cm	16106936
Surgical fenestration drape (IS) 50cm x 50cm	16107202
Surgical fenestration drape (IS) 50cm x 60cm	16107302
Surgical fenestration drapes (IS) 75cm x 75cm	16107402
Surgical fenestration drape (IS) 75cm x 90cm	16107502
Surgical fenestration drape (IS) 75cm x 90cm (lateral adh.)	16107592
Surgical fenestration drape (IS) 50cm x 75cm	16107602
Surgical fenestration drape (IS) 100cm x 100cm	16107802
Surgical split sheets "U" (IS) 120cm x 130cm	16107902
Surgical split sheets "U" (IS) 120cm x 180cm	16108002
Surgical split sheets "U" (IS) 120cm x 150cm	16108102
Surgical split sheets "U" 150cm x 200cm	16108202
Surgical drape in "U" 150x200cm Standard	16108213
Surgical split sheets "U" 220cm x 260cm	16108402
Surgical split sheets 220cm x 260cm Std	16108413
Surgical split sheets "U" (IS) 100cm x 150cm	16108502
Surgical fenestration drape (IS) 60cmx75cm	16109000
Surgical fenestration drape (IS) 75cm x 175cm (fenest. 9x15)	16109102
Surgical fenestration drapes (IS) 150cm x 120cm	16109202
Surgical split sheets in U Orthopaedics 220cm x 300cm	16109402
Surgical split sheets in U Orthopaedics 200cm x 300cm	16109413
Surgical split sheets in U Orthopaedics 220cm x 260cm	16109416
Surgical fenestration drape (IS) 175cm x 250cm	16109502
Reinforced surgical fenestration drape (IS) 200cm x 300cm	16109508
Surgical fenestration drape 3-layers 75cm x 90cm (fenest. 15x20)	16109510
Surgical fenestration drape (IS) 75cm x 90cm (fenest. 2x20)	16109514
Surgical fenestration drape (IS) 75cm x 90cm (fenest. 15x20)	16109516
Reinforced surgical fenestration drape (IS) 200cm x 300cm (fenest. 15x20)	16109518



Surgical fenestration drape (IS) 150cm x 120cm	16109602
Surgical fenestration drape (IS) 175cm x 280cm	16109603
Surgical split drape "U" 250cm x 150cm (op.10x30cm)	16109704
Surgical split drape "U" 50cm x 40cm (op.8x14cm)	16109706
Surgical fenestration drape (PE-Transl) 50cm x 60cm	16109800

