

# EU Declaration of Conformity

(Regulation 2016/425 regulating Personal Protective Equipments, Annex II)

Mr. Ramón Lorente Royo as Managing Director of CARDIVAIS S.A., domiciled at Parque Tecnológico de Andalucía, C / Severo Ochoa nº 64, C.P. : 29590 de Campanillas (Málaga), manufacturer of the referenced product:

## DECLARES

That the products indicated in the Annex are manufactured by CARDIVAIS S.A. and they are included in Category III Personal Protective Equipment and that their manufacture and design comply with the essential health and safety requirements that are applicable to them according to Regulation 2016/425 Annex II, are subject to the conformity assessment procedure to type based on internal production control plus supervised product checks at random intervals (Module C2) and they offer each and every one of the benefits assigned to them as their own.

**APPLICABLE STANDARDS:** EN 13688:2013, EN 13034:2005+A1:2009, 14126:2003/AC:2004, EN ISO 3071:2006, EN 14362-1:2017, EN 13935-2:2014, EN 14325:2004, EN 530:2010, EN 9073-4:1997, EN 13934-1:2013, EN 863:1995, EN 6530:2005, 22610:2006, 22612:2005, 16603:2004, 16604:2004, ISO/DIS 22611:2003.

That the organization will keep the corresponding technical documentation up to date and will satisfy the obligations described in the Regulations, as well as that it will establish and keep up-to-date a systematic procedure to review the experience acquired, using the appropriate means to apply the necessary corrective measures, including information to the authorities.

That, for all of the above, the products referred to in this statement comply with what is described in Regulation (EU) 2016/425 in compliance with current regulations on the regulation of Personal Protective Equipment and hold the certificate of examination of EU type nº **20/2438/00/0161** granted by AITEX as Notified Body 0161, with address at C / Emilio Plaza 1, Alcoy (Alicante).

A handwritten signature in blue ink, appearing to be "R. Lorente Royo".

November 2020  
Ramón Lorente Royo  
Managing Director

## ANNEX

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Surgical Gown/Personal Protective Equipment *coverline®* and its variations: standard and reinforced models

STANDARD MODEL	
Reference	Description
12102220	Standard Surgical Gown/Personal Protective Equipment M
12102230	Standard Surgical Gown/Personal Protective Equipment L
12102240	Standard Surgical Gown/Personal Protective Equipment XL
12102250	Standard Surgical Gown/Personal Protective Equipment XXL
REINFORCED MODEL	
Reference	Description
12112220	Reinforced Surgical Gown/Personal Protective Equipment M
12112230	Reinforced Surgical Gown/Personal Protective Equipment L
12112240	Reinforced Surgical Gown/Personal Protective Equipment XL
12112250	Reinforced Surgical Gown/Personal Protective Equipment XXL