RACLAC®
NEW GENERATION GLOVES

EU Declaration of Conformity

Manufacturer	RACLAC, S.A. Rua da Ribela, nº 600, 4770-170 Cruz, Vila Nova de Famalicão - Portugal
SRN of Manufacturer	PT-MF-000004547

We herewith declare, under our sole responsibility, that the below mentioned products:

Product Description	Blue Nitrile Examination Gloves, powder-free
Registered Brand	Rubbergold®
Reference	FP.RB1301-XS | FP.RB1301-S | FP.RB1301-M | FP.RB1301-L | FP.RB1301-XL
Basic UDI-DI	560033446EXAMGLOVESYT

They are classified as medical device of class I non-sterile device in accordance with the rules contained in Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. They meet the general safety and performance requirements established in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 and the European harmonized standards EN 455-1:2000; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009, ISO 10993-5:2009; ISO 10993-10:2010; EN ISO 20417:2021; EN ISO 14971:2019; ISO 15223-1:2021

They are also classified as personal protective equipment of category III in accordance with Annex I of Parliament Regulation (EU) 2016/425 of the European Parliament of the Council of 9 March 2016. They meet the essential health and safety requirements established in Annex II of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 and harmonized European standards EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2019, EN 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, ISO 16604:2004.

The personal protective equipment has been subjected to the procedure set out in EU Type Examination - Module B under the supervision of BSI Netherlands Notified Body 2797, which issued the EU Type Examination Certificate CE 722394 and is subject to the assessment procedure of conformity Module C2 – conformity to type based on internal production control plus supervised product checks at random intervals under the supervision of BSI Netherlands Notified Body 2797 which issued the EU Type Examination Certificate CE 722395.

BSI Netherlands
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This declaration is supported by the Quality Management System approval to EN ISO 9001:2015 under certificate PT18/06417, issued by SGS ICS and EN ISO 13485:2016 under certificate ES15/93800, issued by SGS UK.

Cruz, 22th December 2021

Authorized signature:

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