



EU DECLARATION OF CONFORMITY

Manufacturer: Berner Ltd.
Hitsaajankatu 24
00810 Helsinki Finland

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand: Bea PRO Nitrile Glove
Type: nitrile, powder free, blue, for single use
Sizes: XS-XL
REF: BPNG1001, BPNG1002, BPNG1003, BPNG1004, BPNG1005
Basic UDI-DI: 641450BPNGGC

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455- 3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

Bea PRO Nitrile Glove is also classified as Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

Bea PRO Nitrile Glove described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/12470-05/E05-01 issued by notified body: Satra Technology Europe Limited (2777), address: Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland.

Bea PRO Nitrile Glove is subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body: Satra Technology Europe Limited (2777), Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland.

Signed on the behalf of the Manufacturer:

Date and place of issue:

19.4.2023 Helsinki