



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 Vinyl Glove

Type: vinyl, powder free, clear, for single use

Sizes: XS-XL

REF: BPVG1001, BPVG1002, BPVG1003, BPVG1004, BPVG1005

Basic UDI-DI: 641450BPVGH4

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 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

Bea PRO Vinyl 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 ISO 21420:2020, EN 16523-1:2015+A1:2018, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2019, EN ISO 374-5:2016.

Bea PRO Vinyl Glove described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/14715-03/E23-01 issued by notified body: Satra Technology Europe Limited (2777), address: Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Bea PRO Vinyl Glove is subject to the conformity to type based on quality assurance of the production process (Module D) 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: Helsinki 9.8.2023