

EU Declaration of Conformity

PPE

Type

552

Spectacles - provided of ophthalmic bifocal polycarbonate lenses -

Univet S.r.l.

Operational headquarters | Via G. Prati 87, 25086 - Rezzato (BS) - Italy

This declaration of conformity is issued under the sole responsibility of the manufacturer Univet S.r.l.

who

Declares that Personal Protective Equipment

code

552.00.00.97-150 - Spectacles - provided of ophthalmic bifocal polycarbonate lenses -

is in conformity with the relevant Union harmonisation legislation

(EU) 2016/425 Regulation

2001/95/EC Directive

Standard EN166:2001

Standard EN ISO 8980-1:2017

furthermore, it complies with the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 regarding medical devices and it is classified as a Class I medical device, intended to compensate for a visual defect.

Basic UDI-DI: 803366182COR0015L

the notified body CERTOTTICA Scarl - Zona Industriale Villanova I - 32013 Longarone (BL) - Italia (number 0530) performed the EU Type-examination (Module B) and issued the EU Type-examination certificate AC 23212 Rev.00

Signed for and on behalf of | Univet S.r.l.

Rezzato,
16/09/2023
Dott. Paolo Portesi
CEO

