

EU Declaration of Conformity

PPE

Type

571.P0.05.98-250

Spectacles - provided of ophthalmic single vision 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

571.P0.05.98-250 - Spectacles - provided of ophthalmic single vision polycarbonate lenses -

as resulting from the assembly of

code

571.00.05.99 - Frame deployable for the manufacturing of ophthalmic protective spectacles in combination with ophthalmic lenses - PPE Component

with

code

C000002M - Ophthalmic single vision polycarbonate lenses - PPE components

is in conformity with the relevant Union harmonisation legislation

(EU) 2016/425 Regulation

2001/95/EC Directive

Standard EN ISO 8980-1:2017

Standard EN166:2001

Standard EN170:2002

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.

Single registration number (SRN): IT-MF-000030077

Basic UDI-DI: 8057147PRE002TS

With regard to - PPE component - code - 571.00.05.99

the notified body ECS GmbH – Obere Bahnstraße 74 - 73431 Aalen - Germany (number 1883) performed the EU Type-examination (Module B) and issued the EU Type-examination certificate C2701.3U

With regard to - PPE component - code - C000002M

the notified body ECS GmbH - Hüttfeldstraße 50 - 73430 Aalen - Germany (number 1883) performed the EU Type-examination (Module B) and issued the EU Type-examination certificate C1126.13U

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

Rezzato,
04/06/2024
Dott. Paolo Portesi
CEO

