

Appendix 1. DECLARATION OF CONFORMITY

Concerning the council directive on medical devices.

We:

Trade One BV
De Corridor 14j
3621ZB Breukelen

declare entirely under our own responsibility:

1- We are the manufacturers of the product:

Eyezoo eyepatch

Batch no: all batch numbers of this type

to which this declaration refers.

2- The product has been designed and built conforming with the requirements of the regulation on medical devices REGULATION (EU) 2017/745, following the procedure of *annex VII of this regulation.

4- The product has been designed and built in accordance with the European Standards:

NEN-EN-ISO 14971:2019

Medical devices - Application of risk management to medical devices

NEN-EN-ISO 15223-1:2016

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Signed at Abbekerk.

Date: 26-10-2022

Technical file drafted by Avier Ingenieurs: MED-VI 2022001

Signed by: Tjeerd Lotens

Function: Director

