EC Declaration of Conformity

Medical Device Directive 93/42/EEC, Annex VII

Name of manufacturer: **Advanced Ophthalmic Systems Ltd (AOS)**
Address of the manufacturer: **The Old Rectory, Church Street, Weybridge, Surrey, KT13 8DE, UK**
Name of medical product: **AOS V3**

Type of medical product: **Medical software**

Intended use of medical product: AOS is a standalone software which allows opticians, orthoptists, optometrists and ophthalmologists to analyse images of the anterior part of the eye which include cornea, conjunctiva, vessels and eye lid.

Authorised European Representative: Medical Device Safety Service (MDSS) Gmbh. Schiffgraben 41. 30175 Hannover. Germany.

Classification: **Medical product is class I (rule 12 MDD)**

confirms that the product AOS that bear the CE marking conform to the Essential Requirements defined within Annex I of the European Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC, concerning medical devices.

Harmonized standards:

- EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- BS EN 62304:2006+A1:2015 - Medical device software – Software life cycle processes
- BS EN 62366-1:2015+A1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2021 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
- ISO 20417:2021 - Information supplied by the manufacturer of medical devices

This declaration is valid and will remain current, unless modified, until 27th May 2024.

Date: 23rd March 2021

Name and Role of Authorized Signatory: Gerard Kool – Director / Management Representative

Gerard Kool
Digitally signed by Gerard Kool
Reason: I am the author of this document
Date: 2022.05.12 15:25:15 +01'00'

Authorized Signature: