[Company header]
[business name and address]

DECLARATION OF CONFORMITY

by Assemblers of Individually Prescribed Corrective Spectacles

I declare that I assemble spectacle frames and lenses to the requirements of UK MDR 2002 Regulation 14 (Article 12 of Directive 93/42/EEC) and that I work in accordance with the process described below.

Signed:…… Date ……

Name of organisation……..

Notes:

a) Mutual Compatibility

All UKCA and CE marked frames and lenses are designed and manufactured to be mutually compatible as a result of the process of assembly (glazing). The essential mutual compatibility of frames and lenses has been established over many years and can be judged by a qualified optician or a suitably trained technician. As part of the process of assembly, we adapt each UKCA or CE marked lens or pair of lenses, so that they fit, and are compatible with, the UKCA or CE marked frame.

We maintain a file of manufacturers' instructions. Whenever manufacturers of frames and/or lenses issue instructions, which are at variance with our normal process of assembly, we follow those instructions.

b) Packaging and Relevant Information

Our professional practice and assembly facility are co-located. All parts and/or assembled spectacles are placed in trays or bags to ensure that they remain undamaged during all processes and until collection by the practice from the assembly facility.

Additional information is included where appropriate, i.e. when supplying new or high technology lens or treatment. This normally takes the form of a user instruction from the manufacturer. Professional staff give clinical advice and any cleaning and care advice that is necessary.

Warranty and any other information may be included as appropriate.

c) Internal Control

Internal control forms part of our ordering and processing system. It is documented and consists of:

- a review of the prescription and the order for assembly
- the selection of the lenses (where we have a choice)
- the process of assembly
- continual inspection of the process of the assembly

d) Devices and Classifications

Device	Classification
Prescription Spectacles	
Ophthalmic spectacle frames	Class I Medical Device
Opthalmic lenses	Class I Medical Device

Medical devices will fall into Class 1 of any of the following:

- Class I CE marked medical devices as required by Regulation 14(1) of the Medical Devices Regulations 2002 (Directive 93/42/EEC) (for devices that have been CE marked prior to 26 May 2021)
- Class I UKCA marked medical devices as required by the Medical Devices Regulations 2002 (England, Wales and Scotland)
- Class I CE marked medical devices as required by the EU Medical Devices Regulation (2017/745) (MDR) (Northern Ireland)