

1. CE Communication towards customer

Prescription reading glasses are identified as a Class 1 medical device. This means devices have to be compliant to the Medical Devices Directive (93/42/EEC), and must bear the CE mark. For class 1 devices, self-certification by the manufacturer is appropriate to bring the product to market, and no involvement of a Notified Body is required. Testing, as described in ISO 12870, must be performed and documented by the manufacturer or by one of the agencies listed below (non-exhaustive list):

- Certottica (Italy)
- Laboratoire Alutec (France)
- Inspec International (UK)
- ...

In order to be compliant to the Medical Devices Directive the manufacturer must put together Technical file for the product. Materialise can provide supporting documentation for this Technical File.

The manufacturer is the natural legal person with the responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The company who produces is not necessarily legally responsible for performance of device on the market.

Overall the manufacturer is legally responsible and liable for the performance of the final device. Additionally he holds the complete technical file of the device and is responsible for the post-market activities.

Considering that Materialise does not manufacture/control the FINAL device (frame + lenses), the CE-marking must be done by the customer.

The test was applied and approved on the SEIKO Xchanger by INSPEC international. Only the test for the frame without lenses were completed. As certain of the results are design specific they cannot be extrapolated to other models.

ISO 12870 does not state a specific protocol regarding the general physiological compatibility. Therefore Materialise based themselves on the Oekotex 100 standard CLASS 1 requirements for skin contact of wearable textiles. The result demonstrate that the parts, prepared according to the manufacturing protocol, successfully passed the test.