

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**OPHTECS Europe B.V.
Marithaime 20
6662 WD Elst
Netherlands**

for the scope

rigid contact lenses

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-02-26
Valid until	2024-05-26
Registration no.	D1016200002
Report no.	P19-01836-166101
Stuttgart	2020-02-26



Head of Certification Body



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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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