EC CERTIFICATE

Certificate No 1991/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

OPTIKON 2000 SPA

00138 ROMA (RM) - VIA DEL CASALE DI SETTEBAGNI 13 (ITA) - Italy

manages in the factory of:

00138 ROMA (RM) - VIA DEL CASALE DI SETTEBAGNI 13 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Ophthalmic surgical equipment

Ophthalmic diagnostic equipment

Single use ophthalmic surgical accessories

Reusable ophthalmic surgical accessories

Ophthalmic diagnostic accessories

Ophthalmic procedure kits

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM17-0014306-01; DM18-0026831-01; DM18-0025372-01; DM18-0027164-01; DM18-0032811-01; DM18-0032046-01; DM19-0037196-01; DM19-0037631-01; DM19-0046043-01; DM19-0044799-01; DM19-0046223-01; DM20-0052564-01; DM20-0057385-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2018-05-02
Updated:	2021-03-18
Substitution Date:	2020-11-27
Expiry Date:	2023-09-19

IMQ

EC CERTIFICATE

Certificate No 1991/MDD

Annex

Ophthalmic surgical equipment

Ophthalmic diagnostic equipment

Single use ophthalmic surgical accessories

Reusable ophthalmic surgical accessories

Ophthalmic diagnostic accessories

Ophthalmic procedure kits

Type ref. as to document 'Annex of EC Certificate no. 1991/MDD - Device List' rev. 01 dated 2021/03/18; this annex is integral and substantial part of this certificate.

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IMQ