CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

OPKO Health Spain, SLU

Plaza Europa, 13-15 Local 2
ES – 08908 L'Hospitalet De Llobregat (Barcelona)
Blanquers, 85
ES – 17820 Banyoles (Girona)
Llorer, 5 (Polígono Industrial Jardí)
ES – 17843 Palol de Revardit (Girona)

has established and applies a quality management system
for the following scope:

Design, production, storage and distribution of sterile ophthalmic devices. Storage and distribution of implantable medical devices for intra-articular, tendons and ligaments injection and gynecological devices.

Through an Audit, Report No. 28113356 001, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0360904**.

This Certificate is valid from 2019-09-15 to 2022-09-14.

The reference date for all the next audits is (day-month): 03-07.

Milan, 2019-09-15. First Certification: 2009-09-15

The certification responsible: Cesare Gentile
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 083A SGA N° 052D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement

TÜVRheinland CERTIFIED

Management System EN ISO 13485:2016

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