EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2066395-1
Manufacturer:	Kai Industries Co., Ltd. 1110 Oyana, Seki-shi, Gifu, 501-3992, Japan
EUDAMED Single Registration No.:	JP-MF-000016663
Products:	Products of class IIa: Q020101 - OPHTHALMIC MICROKNIVES A010203 - CUTANEOUS BIOPSY NEEDLES AND KITS
Authorized representative(s):	Kai Europe GmbH Kottendorfer Straße 5, 42697 Solingen, GERMANY

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-12-05

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	150264149-307
Effective date:	2024-12-05
Expiry date:	2029-12-04
Issue date:	2024-12-05

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This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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