

CERTIFICATE

for a management system as per

EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021

Evidence of conformity has been furnished.

WIRTHWEIN

Wirthwein Medical GmbH & Co. KG Bahnhofstraße 80 64367 Mühltal/Nieder-Ramstadt / Germany incl. the locations according to the annex

Scope :

Design, development, production, assembly and finishing of plastic components and systems for medical technology



Certificate registration No.: 73 105 5377

Certificate valid from: 2025-04-11 **to:** 2025-10-30

Start of certification cycle: 2023-12-08



CKS / Deutsche Akkreditierungsstelle D-ZM-14137-01-00





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 This certification confirms the introduction and maintenance of the Management

 system specified above and is monitored regularly. The current validity is verifiable at

 www.proficert.de. Original certificates contain a glued hologram.

 TÜV Technische Überwachung Hessen GmbH, Robert-Bosch-Strasse 16, 64293 Darmstadt,

 Germany Phone +49 6151/600331
 Rev-GB-2408

 Translation of German original

Dr. M. Ponick Head of Certification body Release: Darmstadt 2025-04-11 Certification Body of TÜV Hessen

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ANNEX



Associated Sites

Locations of the Wirthwein Medical GmbH & Co. KG

An der Papiermühle 2 64367 Mühltal/Nieder-Ramstadt Germany

Röhrstraße 1 64372 Ober-Ramstadt Germany

Scope of the location

Development, production, assembly and finishing of plastic components and systems for medical technology

Production and assembly of plastic components and systems for medical technology

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Head of Certification body Release: Darmstadt 2025-04-11 Certification Body of TÜV Hessen



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