

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.



Certificate registration No.:

73 105 5377

Certificate valid from:

2025-10-31 **to:** 2028-10-30



WIRTHWEIN

Wirthwein Medical GmbH & Co. KG

Bahnhofstraße 80

64367 Mühlthal / Deutschland

incl. the operating sites according to the annex

Scope :

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



Page 1 of 2

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. Ponick

Dr. M. Ponick
Head of Certification body

Release: Darmstadt 2025-09-29
Certification Body of TÜV Hessen



Associated Sites

Wirthwein Medical GmbH & Co. KG

Bahnhofstr. 80
64367 Mühltal / Germany

Scope of application:

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

An der Papiermühle 2
64367 Mühltal / Germany

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

Röhrstraße 1
64372 Ober-Ramstadt / Germany

Production and assembly of plastic components and systems for medical technology

Certificate registration No.:

73 105 5377

Certificate valid from:

2025-10-31 to: 2028-10-30

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



Dr. Ponick

Dr. M. Ponick
Head of Certification body
Release: Darmstadt 2025-09-29
Certification Body of TÜV Hessen