

# CERTIFICATE

for a management system as per

**ISO 13485:2016**  
**EN ISO 13485:2016+AC:2016**

Evidence of conformity has been furnished.

## **WIRTHWEIN MEDICAL**

Wirthwein Medical GmbH & Co. KG  
Bahnhofstraße 80, 64367 Mühlthal / Germany

incl. business premises:

An der Papiermühle 2, 64367 Mühlthal / Germany  
Röhrstraße 1, 64372 Ober-Ramstadt / Germany

scope:

Design, development and production of plastic parts for the  
Medical technology in injection molding and blow molding,  
mold making, assembly and finishing, clean room technology  
in production and assembly.

Certificate registration No. **73 105 5377**

Certificate valid from 2022-10-31 to **2024-05-26**

Audit report No. 4403 2678



Deutsche  
Akkreditierungsstelle  
D-ZM-14137-01-01

*Dr. M. Poidt*

Darmstadt, 2022-10-31  
Certification body of TÜV Hessen  
– Head of Certification body –

Translation of German original