

DMSZ

C E R T I F I C A T E

DMSZ Deutsche Managementsystem Zertifizierungsgesellschaft mbH

hereby certifies that the company



Wirthwein Medical GmbH & Co. KG

Bahnhofstraße 80
64367 Mühlthal
Germany

with the units as listed in the annex
for the scope

**Development/design, mould making, production of plastic parts in injection moulding and blow
moulding, assembly/finishing, clean room technology in production and assembling areas**

has implemented and maintains an

**Quality management system for primary packaging materials for medical products -
particular requirements for the application of ISO 9001:2015 according to Good
Manufacturing Practice (GMP)**

An audit, documented in a report, has verified that this management system fulfills the requirements of the
following standard:

DIN EN ISO 15378:2018

This certificate is valid from 2025-11-25 until 2028-10-30

Certificate Registration No.: GMP 01266-Z04804

Griesheim, Germany, 2025-11-25



Hans-W. Lortz
Hans-Werner Lortz
Head of Certification Body

DMSZ

Annex to Certificate Registration No.: GMP 01266-Z04804 of the company Wirthwein Medical GmbH & Co. KG

Units

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

Scope

Development/design, mould making, production of plastic parts in injection moulding and blow moulding, assembly/finishing, clean room technology in production and assembling areas

Wirthwein Medical GmbH & Co. KG
Röhrstraße 1
64372 Ober-Ramstadt
Germany

Production of plastic parts in blow moulding, assembly/finishing, clean room technology in production and assembling areas

Wirthwein Medical GmbH & Co. KG
An der Papiermühle 2
64367 Mühlthal
Germany

Mould making, production of plastic parts in injection moulding, assembly/finishing, clean room technology in production and assembling areas

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