

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.

kontron

Kontron Europe GmbH

Gutenbergstraße 2

85737 Ismaning / Germany

incl. the locations according to the annex

Scope :

Development, sales, production and service of
IoT/embedded computer assemblies, devices and systems
for active medical devices, as well as development services
on behalf of customers



Certificate registration No.:

73 105 8110

Certificate valid from:

2025-05-09 **to:** 2027-04-28

Start of certification cycle:

2024-04-29



Deutsche
Akkreditierungsstelle
D-ZM-14137-01-00



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

2025-05-09

Certification Body of TÜV Hessen

ANNEX



Associated Sites

Kontron Europe GmbH

Lise-Meitner-Straße 3-5
86156 Augsburg / Germany

Scope of application for this location:

Development, sales, production and service of
IoT/embedded computer assemblies, devices and systems
for active medical devices, as well as development services
on behalf of customers

Kontron Europe GmbH

Heinrich-Barth-Str. 1-1a
66115 Saarbrücken / Germany

Scope of application for this location:

Development of IoT/embedded computer assemblies,
devices, systems and software for active medical devices,
as well as Development services on behalf of customers

Kontron Europe GmbH

Robert-Bosch-Straße 17
93426 Roding / Germany

Scope of application for this location:

Development and distribution of IoT/embedded computer assemblies,
devices, systems and software for active medical devices,
as well as development services on behalf of customers

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Page 2 of 2

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