

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Mediscan GmbH & Co KG

Scope of certification:

Sterilization of medical devices by electron beam and x-ray.
Research and development in connection with electron beam and x-ray for sterilization of medical devices.

Certified location:

Bad Haller Straße 34, 4550 Kremsmünster, Austria
(further locations see annex)

has established and maintains a quality management system according to the above-mentioned standard. The quality management system also complies with the applicable requirements of EN ISO 11137-1:2020. The conformity was adduced with audit report no. 50149-Z8-00.

Certificate registration no.: 50149-15-01_EN
Validity of previous certificate: 2023-04-14

Certificate valid from: 2023-05-08
Certificate valid to: 2026-04-14


Karin Leicht

DEKRA Certification GmbH, Stuttgart, 2023-05-08



Annex to the Certificate No. 50149-15-01

valid from 2023-05-08 to 2026-04-14

The following locations/companies belong to the certificate above:

Headquarters		Scope of certification
		see page 1
at the following locations/at the companies at the following locations		Scopes of certification
1.	Mediscan GmbH & Co KG Bad Haller Straße 44 4550 Kremsmünster Austria	Sterilization of medical devices by electron beam and x-ray. Research and development in connection with electron beam and x-ray for sterilization of medical devices.
2.	Mediscan GmbH & Co KG Im Forschungszentrum 2444 Seibersdorf a.d. Leitha Austria	Sterilization of medical devices by gamma irradiation. Research and development in connection with gamma irradiation for sterilization of medical devices.



K. Leicht

Karin Leicht

DEKRA Certification GmbH, Stuttgart, 2023-05-08