

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-21451-01-00 according to DIN EN ISO/IEC 17025:2018¹

Valid from: 19.10.2022

Date of issue: 19.10.2022

Holder of certificate:

**SD Mechatronik GmbH
Fritz-Krause-Straße 8
83620 Feldkirchen-Westerham**

Field: Medical products

Testing areas/Specimen: Physical testing of medical products as well as dental implants

Abbreviations used: see last page

This document is a translation. The definitive version is the original German annex to the accreditation certificate.
The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<https://www.dakks.de/en/content/accredited-bodies-dakks>

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| Testing Area | Test item Device (category) | Type of testing Test | Regulation Testing method |
|----------------|---|--|---|
| Physical tests | Anaesthetic and re-spiratory equipment - Breathing sets and connectors | Test to check conformity regarding - Safety - Leakage - Flow resistance - Compliance | DIN EN ISO 5367 Annex C and D Annex E Annex F and G Annex H |
| | Dental Implants | Fatigue test | DIN EN ISO 14801 |

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Regulations:

| | |
|----------------------------|---|
| DIN EN ISO 5367 : 2015-02 | Anaesthetic and respiratory equipment – Breathing sets and connectors (ISO 5367:2014); German version EN ISO 5367:2014 |
| DIN EN ISO 14801 : 2017-03 | Dentistry – Implants – Dynamic loading test for endosseous dental implants (ISO 14801:2016); German version EN ISO 14801:2016 |

Abbreviations used:

| | |
|-----|---|
| DIN | Deutsches Institut für Normung (German Institute for Standardization) |
| EN | Europäische Norm (European Standard) |
| ISO | International Organization for Standardization |

¹ DIN EN ISO/IEC 17025:2018-03 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017); German and English version EN ISO/IEC 17025:2017

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