EU Quality Management System Certificate FI23/00000052

The management system of

Pausch Medical GmbH

Graf-Zeppelin-Straße 1,
91056 Erlangen,
Germany
SRN: DE-MF-000011315

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products:
Devices for Urogenital System

Certification is based on decision FI23/08128P0
Previous certificate number: N/A
Change in between this certificate and previous one: N/A
Devices covered, their intended purposes, risk classification, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 25 October 2023 until 24 October 2028 and remains valid subject to satisfactory surveillance audits.
Issue 1 Certified since 25 October 2023.
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Seppo Vahasalo, NB Manager

SGS FIMKO OY
Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
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FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

Pausch Medical GmbH

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 1
Sites
Graf-Zeppelin-Straße 1, 91056 Erlangen, Germany Main site

Pausch Medical GmbH

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Attachment 1 of Issue 1

Device or Device Group, EMDN Code	Risk Class	Identification Details and Intended Purposes
U99 Devices for Urogenital System-Other	IIb	Model: Urological X-ray Table Uromat HD - Right hand Intended use: Positioning of patients for radiological diagnostics as well as gynecological and urological diagnostics and therapy
U99 Devices for Urogenital System-Other	IIb	Model: Urological X-ray Table Uromat HD - Left hand Intended use: Positioning of patients for radiological diagnostics as well as gynecological and urological diagnostics and therapy

The certification decision is based on the following:

Report Identification and Date
PAUSCH Medical_V1-S2_FPMDREG3019 - MD Audit Report Ver E_Rev. 1_2023-05-11_signed, dated 2023-05-11. Pausch - FPMDREG3020 - MDR Technical Documentation Assessment Report Ver E 20231025, dated 2023-10-25.

Conditions for or limitation to the validity of the certificate
N/A

EU Authorised Representative
N/A