EU Quality Management Certificate

This is to certify that the company

Effectum Medical AG

Kirchgasse 11
4600 Olten
Switzerland

SRN: CH-MF-000012474

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	534922 MDR2017Q
Certificate ID	1000184044
Effective date	2024-10-10
Expiry date	2028-01-10
Frankfurt am Main,	2024-10-10

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000012474
Certificate ID: 1000184044

Authorised Representative of the company:

MED-RAS GmbH	Emergo Europe	Interlinked AB
Eichenallee 8H 21521 Wohltorf Germany	Westervoortsedijk 60 6827 AT Arnhem Netherlands	Regeringsgatan 82 11139 Stockholm Sweden
SRN: DE-AR-000006211	SRN: NL-AR-000000116	SRN: SE-AR-000043689

Device categories and variants covered by this certificate:

Device category:	**MDN 1202 Non-active non-implantable devices for administration, management and removal of substances including dialysis products.**
Product name:	Picleo
Risk classification:	Is
Basic-UDI-DI:	7640255020489
Intended purpose:	Picleo paediatric dosing device is intended to facilitate the intravitreal administration of a single 10 µl nominal dose of Eylea® 40 mg/ml medicinal product in pre-filled syringe by delivering a fixed volume.
Authorised Representative:	Emergo Europe

Device category:	**MDA 0308 Active non-implantable devices for wound and skin care**
Product name:	ActivCellpen
Risk classification:	IIa
Basic-UDI-DI:	764025502ACT100WU
Intended purpose:	The product is intended to reduce microorganisms on the skin or wound and thus promote wound healing
Authorised Representative:	MED-RAS GmbH

Device category:	**MDA 0315 Software**
Product name:	OptiBP
Risk classification:	IIa
Basic-UDI-DI:	764025502TD0123Y
Intended purpose:	OptiBP is a software-only mobile medical application that is intended to be used in a compatible mobile computing platform (e.g. a smartphone or a tablet). OptiBP is intended to measure and display blood pressure (systolic and diastolic) based on a photoplethysmography (PPG) signal. The device extracts the PPG signal from optical data captured from capillary fingertip tissue, from a user's index or middle finger, when placed over the mobile platform's camera. The device is intended for use in adults aged 18 years and older. The blood pressure estimates displayed by OptiBP are intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation from a qualified healthcare professional.
Authorised Representative:	MED-RAS GmbH

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Device category:	**MDA 0313 Active, non-implantable protheses and devices for rehabilitation**
Product name:	Hall-U-Sana
Risk classification:	IIa
Basic-UDI-DI:	764025502Hall-U-Sana4N
Intended purpose:	The intended use of the Hall-U-Sana continuous passive motion (CPM) device is the support of post-operative treatment after surgery through of the 1st ray through passive movement of the big toe. Passive movement of the toe during post-operative treatment reduces the risk of stiffness and remaining pain and prolonged postoperative swelling after surgery.
Authorised Representative:	MED-RAS GmbH

Device category:	**MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis**
Product name:	Magnes Nushu
Risk classification:	IIa
Basic-UDI-DI:	764025502Magnes-NuShuXY
Intended purpose:	Magnes Nushu is a medical device that enables patients to collect data on their gait and share this data with healthcare professionals (HCPs). Magnes Nushu can help patients with gait deficits by providing them notifications via vibrations on how they walk to assist normal walking. Magnes Nushu Web Application is intended to be used by HCPs to visualize and track the walking parameters collected by patients using Magnes Nushu. The data collected by Magnes Nushu can be used to infer changes in the condition of patients.
Authorised Representative:	MED-RAS GmbH

Device category:	**MDA 0315 Software**
Product name:	VisionOne
Risk classification:	IIa
Basic-UDI-DI:	764025502TD01648
Intended purpose:	The VisionOne software is intended to measure a patient's visual field, configure perimetry tests and display test results which are used to aid in the detection, diagnosis and monitoring of ocular and neurological diseases.
Authorised Representative:	Emergo Europe

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Device category:	**MDN 1202 Non-active non-implantable devices for administration, management and removal of substances including dialysis products.**
Product name:	ReLink Care
Risk classification:	Is
Basic-UDI-DI:	764025502TD0184C
Intended purpose:	ReLink Care is a breakaway connector for intravenous (IV) therapy use. ReLink Care separates into two self-sealable parts when an excessive tension is exerted on the IV line, thereby avoiding accidental dislodgement of the catheter, spillage of fluids, and patient injury. The parts are reconnectable after disinfection.
Authorised Representative:	Interlinked AB

Device category:	**MDN 1202 Non-active non-implantable devices for administration, management and removal of substances including dialysis products.**
Product name:	ReLink Drain
Risk classification:	Is
Basic-UDI-DI:	764025502TD0194E
Intended purpose:	ReLink Drain is a breakaway connector for nephrostomy drainage catheter use. ReLink Drain separates into two self-sealable parts when an excessive tension is exerted on the nephrostomy drainage tube, thereby avoiding accidental dislodgement of the nephrostomy catheter, spillage of fluids, and patient injury. The parts are reconnectable after disinfection.
Authorised Representative:	Interlinked AB

Examinations and tests performed:
534922_A209093MED_01 dated 2022-04-23
534922_A211766MED_03 dated 2023-06-25
534922_A209093MED_02 dated 2023-05-25
534922_A211371MED_04 OptiBP vom 2023-08-13
534922_A209093MED_05 Hall-U-Sana dated 2024-01-26
534922_ A212979MED_06 Magnes Nushu dated 2024-03-10

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

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Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-11	170779006	Change of purpose and addition oft he product „ActivCellpen“
02	2023-07-20	1000127456	Add the second Authorised Representative and change of purpose of purpose from "ActivCellpen"
03	2023-08-07	1000131476	Addition of the product “OptiBP”
04	2023-08-24	1000132972	Addition of the product “Hall-U-Sana”
05	2024-02-16	1000167620	Addition of the product „Magnes Nushu“ and correction of the intended use of the products „OptiBP“, „Hall-U-Sana“ and „ActivCellpen“. Change of the product name from "Micro Dosing Device“ to „Picleo“.
06	2024-04-25	1000171826	Addition of the products „VisionOne“, „ReLink Care“, „ReLink Drain“