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.

For placing of devices of class IIa, IIb or III 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	1000132972
Effective date	2023-08-24
Expiry date	2028-01-10
Frankfurt am Main,	2023-08-24

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)

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000012474
Certificate ID: 1000132972

Authorised Representative of the company:

MED-RAS GmbH

Eichenallee 8H
21521 Wohltorf
Germany

SRN: DE-AR-000006211

Emergo Europe

Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

SRN : NL-AR-000000116

Device categories covered by this certificate:

Device category:	**MDN 1202 Non-active non-implantable devices for administration, management and removal of substances including dialysis products.**
Risk classification:	Is
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**
Risk classification:	IIa
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**
Risk classification:	IIa
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 optically estimate and display blood pressure (systolic and diastolic). Measurement is performed on capillary fingertip tissue placed over the computing platform's camera. The index finger is the recommended site. The device is intended for over-the-counter (OTC)-use in adults above 18 years old. It may not provide accurate results for pregnant women. The blood pressure data displayed by the OptiBP is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.
Authorised Representative:	MED-RAS GmbH

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Examinations and tests performed:
534922_A209093MED_01 dated 2022-04-23
534922_A211766MED_03 dated 2023-06-25

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
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

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-11	170779006	Change of purpose and addition of the product "ActivCellpen"
02	2023-07-20	1000127456	Add the second Authorised Representative and change of purpose from "ActivCellpen
03	2023-08-07	1000131476	Addition of the product "OptiBP"