EU Technical Documentation Assessment Certificate

This is to certify that the company

Effectum Medical AG

Kirchgasse 11
4600 Olten
Switzerland

SRN: CH-MF-000012474

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

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

Certificate registration no.	534922 MDR2017B
Certificate ID	1000132973
Effective date	2023-08-24
Expiry date	2028-07-19
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
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Head of Certification Body
(active medical devices)

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Head of Certification Body
(non-active medical devices)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: CH-MF-000012474
Certificate ID: 1000132973

Device categories and variants covered by this certificate:

Device category:	**MDA 0308 Active non-implantable devices for wound and skin care**
Product name:	ActivCellpen
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	CHE-389.095.825
Intended purpose:	The product is intended to reduce microorganisms on the skin or wound and thus promote wound healing.

Device category:	**MDA 0315 Software**
Product name:	OptiBP
Models:	n/a
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 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.

Examinations and tests performed:
534922_A209093MED_02 dated 2023-05-25
534922_A211371MED_04 OptiBP vom 2023-08-13

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-07-20	1000127466	Change of purpose for ActivCellpen
02	2023-08-07	1000131477	Addition of the product "OptiBP"