



3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-AXVI/QS-001

CHA Meditech Co., Ltd.

#102, 103, 202, 204 Migun Techno World I, 199, Techno 2-ro, Yuseong-gu, Daejeon, Republic of Korea

SRN No.: KR-MF-000008782

Name of the Authorized representative

Emergo Europe B.V.

Westervootsedijk 60 6827 AT Arnhem, The Netherlands

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of product without an intended medical purpose:

Dermal Filler (Hyaluronic Acid Filler)

Trade name: see Annex I

Model name: see Annex I

Intended purpose: The device is a dermal filler intended for the correction of moderate to deep facial wrinkles and folds, specifically the nasolabial folds.

MD class III, Rule 8

(detailed list is stated in the annexes)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned product without an intended medical purpose and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned product without an intended medical purpose is stated in the Technical Documentation Assessment Report No. AXVI002_2023 from 2025-12-19, Clinical Evaluation Report No. AXVI002_2023 from 2025-12-19 and Audit Report No. SK-0671/25 from 2025-12-19. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned product without an intended medical purpose. For the placing on the market of the AXVIs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **2026-01-07**
Valid until: **2031-01-07**
First issue: **2026-01-07**
Revision: **00**
History: **in Annex III**



3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-01-07



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-AXVI/QS-001

issued for the company

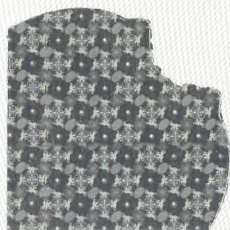
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List of medical devices covered by the EU Quality Management System Certificate:

Trade Name	No	Model Name	Catalogue No
HyaFilia	1	HyaFilia M 1.0	F001F
	2	HyaFilia M 3.0	F003T
	3	HyaFilia M 5.0	F005T
	4	HyaFilia M 5.0	F005
	5	HyaFilia S 1.0	SF001F
	6	HyaFilia S 3.0	SF003T
	7	HyaFilia S 5.0	SF005T
	8	HyaFilia S 5.0	SF005
	9	HyaFilia V 1.0	VF001TF
	10	HyaFilia V 3.0	VF003T
	11	HyaFilia V 5.0	VF005T
	12	HyaFilia V 5.0	VF005
RenewFill	1	RenewFill Classic 1.0	RF001F
	2	RenewFill Classic 3.0	RF003T
	3	RenewFill Petit 1.0	RP001F
	4	RenewFill Petit 3.0	RP003T
	5	RenewFill Grand 1.0	RG001T
	6	RenewFill Grand 3.0	RG003T

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Katarína Tomin Srdošová, PhD.
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List of medical devices covered by the EU Quality Management System Certificate:

Trade Name	No	Model Name	Catalogue No
Dorothy	1	Dorothy 1.0	CMD001F
	2	Dorothy 3.0	CMD003T
	3	Dorothy 3.0	CMD003
	4	Dorothy Petit 1.0	CMDP001F
	5	Dorothy Petit 3.0	CMDP003T
	6	Dorothy Grand 1.0	CMDG001TF
	7	Dorothy Grand 3.0	CMDG003T
SOSUM	1	SOSUM S	SS001F
	2	SOSUM M	SM001F
	3	SOSUM H	SH001TF
	4	SOSUM SOFT	SS003
	5	SOSUM HARD	SH003

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CHA Meditech Co., Ltd.

#102, 103, 202, 204 Migun Techno World I, 199, Techno 2-ro, Yuseong-gu, Daejeon, Republic of Korea

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

The device is a dermal filler intended for the correction of moderate to deep facial wrinkles and folds, specifically the nasolabial folds.

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In Bratislava, Slovak Republic, 2026-01-07
Valid until 2031-01-07

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-AXVI/QS-001

issued for the company

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Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2026-AXVI/QS-001	2026-01-07	AXVI002_2023	Initially issued certificate

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In Bratislava, Slovak Republic, 2026-01-07
Valid until 2031-01-07

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