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

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2024-MDR/TD-069

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea
SRN No.: KR-MF-000037085
Name of the Authorized representative:
Samyang Biopharm Magyarország Kft., Gödöllő, Bláthy Ottó utca 2, 2100, Hungary

This EU Technical Documentation Assessment 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 technical documentation of the medical device:

Absorbable internal hemostat
Model names: see Annex I
Intended purpose: see Annex II
MD class III, Rule 8
Basic UDI-DI: 88062270SG01PP
(detailed list is stated in the annex(es) if applicable)

meets the requirements of technical documentation assessment according to the Chapter II 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 technical documentation assessment of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the abovementioned medical device is stated in the Technical Documentation Assessment Report No. MDR253_2023 from 04.10.2024, Clinical Evaluation Report No. MDR253_2023 from 04.10.2024 and Audit Report No. SK-0681/24 from 30.11.2024. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Technical Documentation Assessment Certificate** applies only to the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **12.12.2024**
Valid until: **12.12.2029**
First issue: **12.12.2024**
Revision: **00**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 12.12.2024

ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2024-MDR/TD-069

issued for the company

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea

List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Product Name	Brand Name	Type	Model / Product Code	Product size (Width x Length)	UDI Code
Absorbable internal hemostat	SurgiGuard®	Original	DMHO201	5 x 7.5 cm	08806227005420
			DMHO202	5 x 35 cm	08806227005529
			DMHO203	10 x 20 cm	08806227005628
			DMHO204	1.25 x 5 cm	08806227005321
		Fabric	DMHN201	5 x 7.5 cm	08806227008629
			DMHN202	7.5 x 10 cm	08806227008025
			DMHN203	15.2 x 22.9 cm	08806227008322
			DMHN204	2.5 x 2.5 cm	08806227008421
			DMHN205	2.5 x 7.5 cm	08806227008520
		Fibrillar	DMHF201	2.5 x 5.1 cm	08806227007523
			DMHF202	5.1 x 10.2 cm	08806227008728
			DMHF203	10.2 x 10.2 cm	08806227008124
		Non woven	DMHS201	2.5 x 5.1 cm	08806227007929
			DMHS202	5.1 x 10.2 cm	08806227008827
			DMHS203	10.2 x 10.2 cm	08806227008223

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 12.12.2024
Valid until 12.12.2029

ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2024-MDR/TD-069

issued for the company

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea

Intended purpose of medical devices covered by the EU Technical Documentation Assessment Certificate:

SurgiGuard® is designed to assist in the control of capillary, venous, and small arterial hemorrhage.

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 12.12.2024
Valid until 12.12.2029

ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2024-MDR/TD-069

issued for the company

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea

Certificate history:

Revision	EU TD Assessment Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2024-MDR/TD-069	12.12.2024	MDR253_2023	Initially granted certification

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 12.12.2024
Valid until 12.12.2029

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2024-MDR/QS-069

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea
SRN No.: KR-MF-000037085
Name of the Authorized representative:
Samyang Biopharm Magyarország Kft., Gödöllő, Bláthy Ottó utca 2, 2100, Hungary

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 medical device:

Absorbable internal hemostat
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class: III, Rule 8
(detailed list is stated in the annex(es) if applicable)

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 medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the Technical Documentation Assessment Report No. MDR253_2023 from 04.10.2024, MD Clinical Evaluation Report No. MDR253_2023 from 04.10.2024 and MD Audit Report SK-0681/24 from 30.11.2024. 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 medical device. For the placing on the market of the MDs 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: **12.12.2024**
Valid until: **12.12.2029**
First issue: **12.12.2024**
Revision: **00**
History: **see Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 12.12.2024

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-069

issued for the company

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea

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

Product Name	Brand Name	Type	Model / Product Code	Product size (Width x Length)	UDI Code
Absorbable internal hemostat	SurgiGuard®	Original	DMHO201	5 x 7.5 cm	08806227005420
			DMHO202	5 x 35 cm	08806227005529
			DMHO203	10 x 20 cm	08806227005628
			DMHO204	1.25 x 5 cm	08806227005321
		Fabric	DMHN201	5 x 7.5 cm	08806227008629
			DMHN202	7.5 x 10 cm	08806227008025
			DMHN203	15.2 x 22.9 cm	08806227008322
			DMHN204	2.5 x 2.5 cm	08806227008421
			DMHN205	2.5 x 7.5 cm	08806227008520
		Fibrillar	DMHF201	2.5 x 5.1 cm	08806227007523
			DMHF202	5.1 x 10.2 cm	08806227008728
			DMHF203	10.2 x 10.2 cm	08806227008124
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			DMHS202	5.1 x 10.2 cm	08806227008827
			DMHS203	10.2 x 10.2 cm	08806227008223

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In Bratislava, Slovakia, 12.12.2024
Valid until 12.12.2029

Katarína Tomin Srdošová, PhD.
Director of NB 2265

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-069

issued for the company

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea

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

SurgiGuard® is designed to assist in the control of capillary, venous, and small arterial hemorrhage.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 12.12.2024
Valid until 12.12.2029

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-069

issued for the company

Samyang Holdings Corporation

MD Plant, 55, Munpyeongseo-ro 18beon-gil, Daedeok-gu, Daejeon, 34302, Republic of Korea

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2024-MDR/QS-067	12.12.2024	MDR253_2023	Initially granted certification

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 12.12.2024
Valid until 12.12.2029