

EC CERTIFICATION

EU Quality Management System Certificate Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Tulip Medical Products, Inc.

4360 Morena Blvd., Suite 100, San Diego, California, 92117, United States

Manufacturer SRN: US-MF-000049097

Authorised Representative:

MedEnvoy Global BV [EN]

33, Prinses Margrietplantsoen, 2595 AM, The Hague

Scope:

Devices channeling substances

Instruments

Certificate Number:

28620236355

Revision:

00

Initial Certification Date:

22 January 2026

Certificate Decision Date:

22 January 2026

Certificate Issue Date:

22 January 2026

Certificate Expiry Date:

30 June 2030



Mikael Hagelin

Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	Stage 1 - ACTY-2022-583264
	Stage 2 - ACTY-2024-228192
Technical Assessment Report Reference	TD00634-001 - GEMS Carraway Harvester

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620236355	22 January 2026	Initial certificate

Certificate Number:
28620236355

Revision:
00

Initial Certification Date:
22 January 2026

Certificate Decision Date:
22 January 2026

Certificate Issue Date:
22 January 2026

Certificate Expiry Date:
30 June 2030



Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

Issued to: Tulip Medical Products, Inc.

Certificate number: 28620236355

Certificate valid from: 2026-01-22

Product list issue date:
22 January 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Devices channeling substances			
Basic UDI-DI: 081912702DCHVST59			
GEMS Carraway Harvester (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Carraway Harvester (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Carraway Harvester (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Carraway Harvester (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Carraway Harvester (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Carraway Harvester (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Miller Speed Harvester (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Miller Speed Harvester (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Sorensen Harvester (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Sorensen Harvester (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tonnard Harvester (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
GEMS Tonnard Harvester (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Carraway Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Miller Speed Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Miller Speed Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Sorensen Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Sorensen Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tonnard Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
GEMS AlphaLuer Tonnard Harvester <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Basic UDI-DI: 081912702DCINF2C			
GEMS Tumescant Infiltrator (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tumescant Infiltrator (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tumescant Infiltrator (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tumescant Infiltrator (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tumescant Infiltrator (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tumescant Infiltrator (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tumescant Infiltrators <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tumescant Infiltrators <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tumescant Infiltrators <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tumescant Infiltrators <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tumescant Infiltrators <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tumescant Infiltrators <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Basic UDI-DI: 081912702DCINJ2L			
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Tulip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Spoon Tip Injector (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS Spoon Tip Injector (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Tulip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Spoon Tip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
GEMS AlphaLuer Spoon Tip Injector <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Basic UDI-DI: 081912702TRANSFERZL			
Disposable Anaerobic Sizing Transfer- (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Anaerobic Sizing Transfer- (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Anaerobic Sizing Transfer - (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Anaerobic Emulsification Transfer- (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Anaerobic Emulsification Transfer- (10 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Anaerobic Sizing Transfer - (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable NanoFat Transfer, Generation 2 - 90° (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable NanoFat Transfer, Generation 2 - 90° (5 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable NanoFat Transfer, Generation 1- Cartridge (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
Disposable NanoFat Transfer, Generation 1- Cartridge (5 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Instruments			
Basic UDI-DI: 081912702JSNAP84			
Disposable Johnnie Snap (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Johnnie Snap (5 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Johnnie Snap (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Johnnie Snap (5 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Johnnie Snap (Single) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22
Disposable Miller Snap (5 Pack) <i>GEMS Soft Harvest System</i>	Class IIa TBD		2026-01-22

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
---------	-------------------------	---------------------------	------------



Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB
Torshamnsgatan 43,
Box 1103, SE - 164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

