Therakos™

Navigating EU Medical Device Regulation

MDR approved

See inside

Understanding Compliant Medical Device Use

Therakos™ CellEx™ PHOTOPHERESIS SYSTEM

EU: European Union; MDR: Medical Device Regulation.

THERAKOS™ CELLEX™ Photopheresis System: MDR-certified

With over **three decades** of clinical evidence and experience in extracorporeal photopheresis (ECP),*[1] Therakos understands the importance of patient safety and regulatory compliance.

The THERAKOS™ CELLEX™ Photopheresis System is the world's **only single, all-in-one, fully integrated** platform for ECP, and has obtained CE Certification under the Medical Device Regulation (EU MDR) 2017/745 for the following indications:[2,3]

- Cutaneous T-Cell Lymphoma (CTCL) in patients >18 years of age
- Acute and Chronic Graft versus Host Disease (aGvHD, cGvHD) >3 years of age
- Solid Organ Transplant (SOT) rejection (heart and lung) >18 years of age

From Medical Device Directive to Medical Device Regulation

On **26th May 2021**, the existing **Medical Device Directive (MDD, 93/42/EEC)** was replaced with a new framework, the **EU Medical Device Regulation (EU MDR 2017/745)**.[4-7]

Medical devices approved under MDD before 26th May 2021 may continue to be used until **31st December 2028**. From this point onwards, any previously certified medical device under MDD, without having a certification under MDR, is no longer approved for use in the EU.[6]

*FDA pre-market approval received 08 April 1987.
CE: Conformité Européene, or European Conformity marking; **EEC:** European Economic Community; **EU:** European Union; **MDD:** Medical Device Directive; **MDR:** Medical Device Regulation.

Important Changes

Under the new regulatory framework, tighter controls ensure medical devices are safe, effective and manufactured under high-quality systems.[4,8] Important changes include:

Enhanced Rigour & Patient Safety: MDR demands comprehensive clinical evaluation of devices. This is an ongoing process of collecting and analysing clinical data to continuously assess the safety and performance of a device for its intended use. It is documented in a **Clinical Evaluation Report**.[4,7,8]

Continuous Monitoring: Requirements for monitoring devices after they enter the market, known as **post-market surveillance**, including product complaint and adverse events reporting.[4]

Traceability & Transparency: A Unique Device Identifier (UDI) allows easier traceability of medical devices. The **EUDAMED database** provides centralised, public access to safety and performance data.[4,8]

Direct Applicability: The new regulations are **directly applicable** and **do not need to be integrated** into national law.[4,5,7] This reduces the risk of discrepancies in the interpretation across the EU.[7]

The Importance of MDR Compliance

Using MDR-certified medical devices establishes the product's safety and efficacy profile under a new set of standards.

Protecting Patients: MDR certified devices meet rigorous safety and performance standards, backed by clinical data and continuous monitoring. This means greater assurance that the device has demonstrated safety and effectiveness.[4,7]

EU: European Union; **EUDAMED**: European Database on Medical Devices; **MDR**: Medical Device Regulation.

MDR Compliance Checklist

To confidently identify MDR-compliant devices and uphold the latest standards, use this quick checklist:

Verify Certification

Refer to the device's 'Declaration of Conformity' to confirm its MDR certification. Remember, all medical devices must be MDR-compliant by 31st December 2028

Consult Instructions for Use

Refer to the device's instructions for use for approved indications and proper usage

Check EUDAMED

Consult the EUDAMED database for comprehensive device information

Confirm with Supplier

If you have any doubts about a device's MDR status, confirm directly with the supplier or manufacturer

For more information on the THERAKOS™ CELLEX™ Photopheresis System, education, and training visit www.therakos.eu.

EUDAMED: European Database on Medical Devices; **MDR:** Medical Device Regulation.

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR THE THERAKOS™ PHOTOPHERESIS PROCEDURE

Indications

The THERAKOS™ CELLEX™ Photopheresis System is indicated for patients older than 18 years of age for the administration of photopheresis in the following:

- Cutaneous T Cell Lymphoma (CTCL)
- Solid Organ Transplant Rejection (SOT) (heart, lung)

The THERAKOS™ CELLEX™ Photopheresis System is indicated in patients older than 3 years of age for the management of:

- Acute and Chronic Graft versus Host Disease (aGvHD, cGvHD)

Contraindications

THERAKOS™ Photopheresis is contraindicated in:

- Patients possessing a specific history of a light sensitive disease.
- Patients who cannot tolerate extracorporeal volume loss or who have white blood cell counts greater than 25,000/mm^3.
- Patients who have coagulation disorders or who have previously had a splenectomy.

Warnings and Precautions

THERAKOS™ Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure. Safety in children has not been established.

- Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image or may not function properly.
- Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft versus Host Disease (GvHD). Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- When prescribing and administering THERAKOS™ Photopheresis for patients receiving concomitant therapy, exercise caution when changing treatment schedules to avoid increased disease activity that may be caused by abrupt withdrawal of previous therapy.

Adverse Events

- Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for hypotension.
- Transient pyretic reactions, 37.7–38.9°C (100–102°F), have been observed in some patients within six to eight hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction.
- Treatment frequency exceeding labelling recommendations may result in anaemia.
- Venous access carries a small risk of infection and pain.

IMPORTANT SAFETY INFORMATION FOR METHOXSALEN USED IN CONJUNCTION WITH THERAKOS™ PHOTOPHERESIS

Consult the 8-methoxypsoralen (Methoxsalen (20 micrograms / mL)) professional leaflet or the oral 8-methoxypsoralen formulation package insert before prescribing or dispensing any medication.

Warnings and Precautions

- Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinoma should be diligently observed and treated.
- Methoxsalen may cause fetal harm when given to a pregnant woman. Women undergoing photopheresis should be advised to avoid becoming pregnant.
- Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic.
- Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

Refer to the package insert for methoxsalen sterile solution (20 micrograms/mL) or the oral 8-methoxypsoralen dosage formulation for a list of all warnings and precautions.

Please refer to the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual for a complete list of warnings and precautions.

References

1. FDA pre-marketing authorization. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P860003. Accessed January 2026. **2.** Knobler R, et al. J Eur Acad Dermatol Venereol. 2020;34(12):2693-2716. **3.** Data on file - Ref-07582. **4.** Regulation (EU) 2017/745, OJ L 117, 5.5.2017, p. 1-233, consolidated version 10.01.2025. Available at: https://eur-lex.europa.eu/eli/reg/2017/745/2025-01-10. Accessed January 2026. **5.** Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12 July 1993, pp. 1-43. Available at: https://eur-lex.europa.eu/eli/dir/1993/42/oj. Accessed January 2026. **6.** Timeline for the Medical Device Regulation (MDR). European Commission. Available at: https://health.ec.europa.eu/document/download/06bb3982-dc01-46aa-95af-d8833c9fcb21_en?filename=timeline_mdr_en.pdf. Accessed January 2026. **7.** Factsheet for healthcare professionals and health institutions. European Commission. December 2024. Available at: https://health.ec.europa.eu/publications/factsheet-healthcare-professionals-and-health-institutions_en. Accessed January 2026. **8.** New EU Rules to Ensure Safety of Medical Devices. European Commission. 2018. Available at: https://health.ec.europa.eu/document/download/3518b8dc-238a-4844-9f80-27aced75173a_en?filename=md_generic_fs_en.pdf. Accessed January 2026.

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