

## **SAFTEY WARNING**

Internal No 2021\_06\_17\_SW

### **WARNING about a non-conform use of the Photopheresis System “UVA PIT System” with a KIT other than the original PIT KIT distributed by PIT Medical Systems GmbH, Am Farrnbach 1, 90556 Cadolzburg, Germany**

**This notice needs to be passed on to all users of the UVA PIT System.**

This warning relates to the UVA PIT Systems manufactured by Med Tech Solutions GmbH, Am Farrnbach 1, 90556 Cadolzburg, Germany certified under the Notified Body MDC (CE 0483).

This letter is to inform you of a non-conform and non-intended use of the UVA PIT System with the LLK-02 KIT manufactured by Pelham Crescent srl, Via Strozziacaponi 92 u 18, Perugia, 06132 Italy.

The responsibility and control of the UVA PIT Systems lies with PIT Medical Systems GmbH, Am Farrnbach 1, 90556 Cadolzburg, Germany.

The company Pelham Crescent srl, as well as their distributors recommend and distribute a KIT with the name LLK-02, KIT per Fotoferesi per Uva Pit System, Photopheresis Kit for Uva Pit, whose label falsely suggests that the manufacturer of the UVA PIT System has tested and approved this KIT for use with the UVA PIT System.

We cannot exclude that Pelham Crescent srl or their distributors of the LLK-02 KITS has also replaced the Operator Manual of the UVA PIT System.

**The manufacturer of the UVA PIT System, Am Farrnbach 1, 90556 Cadolzburg, Deutschland has never verified or validated the use of the UVA PIT System with the LLK-02 KIT.**

- The UVA PIT System combined with the LLK-02 KIT is out-side the original manufacturer intended use.
- The combination of the UVA PIT System with the LLK-02 KIT is a combination without a conformity assessment procedure.
- The system can only be operated with a smart card programmed by the manufacturer of the UVA PIT System therefore the combination device/smart card must have been manipulated.
- We would like to point out that only service personnel trained by the manufacturer of the UVA PIT System may carry out the service.
- Manipulation and service activities by unauthorized service personnel may impair the safetyof the UVA PIT System.

We also confirm that this notice has been communicated to the relevant regulatory authority.  
Please contact us if you have any further questions.

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## **VARNOSTNO OPOZORILO**

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### **OPOZORILO o neskladni uporabi sistema za fotoferozo "UVA PIT System" kompletom, ki ni originalni PIT KIT, ki ga distribuira PIT Medical Systems GmbH, Am Farrnbach 1, 90556 Cadolzburg, Nemčija**

**To obvestilo je treba posredovati vsem uporabnikom UVA PIT System.**

To opozorilo se nanaša na UVA PIT System, ki jih proizvaja podjetje Med Tech Solutions GmbH, Am Farrnbach 1, 90556 Cadolzburg, certificirano pri priglašenem organu MDC (CE 0483).

S tem dopisom vas obveščamo o neskladni in nenamerni uporabi UVA PIT System s kompletom LLK-02 KIT, ki ga proizvaja podjetje Pelham Crescent srl, Via Strozacaponi 92 u 18, Perugia, 06132 Italija.

Za UVA PIT System je odgovorna in ga nadzoruje družba PIT Medical Systems GmbH, Am Farrnbach 1, 90556 Cadolzburg, Nemčija.

Podjetje Pelham Crescent srl in njegovi distributerji priporočajo in distribuira komplet z imeno

LLK-02, KIT per Fotoferesi per Uva Pit System, komplet za fotoferozo za UVA PIT System, katerega oznaka napačno navaja, da je proizvajalec UVA PIT System testiral in odobril ta komplet za uporabo s UVA PIT System.

Ne moremo izključiti, da je družba Pelham Crescent srl ali njeni distributerji kompletov LLK-02 KITS zamenjali tudi priročnik za uporabo UVA PIT System.

**Proizvajalec UVA PIT System, Am Farrnbach 1, 90556 Cadolzburg, Nemčija, ni nikoli preveril ali potrdil uporabe sistema UVA PIT s kompletom LLK-02.**

- UVA PIT System v kombinaciji s kompletom LLK-02 ni v skladu s prvotno predvideno uporabo proizvajalca.
- Kombinacija UVA PIT System s kompletom LLK-02 KIT je kombinacija brez postopka ugotavljanja skladnosti.
- Sistem je mogoče upravljati samo s čipovsko kartico, ki jo programira proizvajalec naprave UVA PIT, zato je bilo treba z napravo/čipovsko kartico manipulirati.
- Opozarjamo, da lahko servisne posege izvaja samo servisno osebje, ki ga je usposobil proizvajalec UVA PIT System.
- Manipulacija in servisne dejavnosti, ki jih izvaja nepooblaščen servisno osebje, lahko ogrozijo varnost UVA PIT System.

Potrjujemo tudi, da je bilo to obvestilo posredovano ustreznemu regulativnemu organu. Če imate dodatna vprašanja, se obrnite na nas.