

Clearance Certificate

Hilotherm GmbH
Wittumweg 38, D-88260 Argenbühl-Eisenharz

confirms that the handling of the Hilotherm device types

HT02 and **HTP1 Pro** with the sales names

Hilotherm Clinic, Hilotherm ChemoCare, Hilotherm Homecare, Hilotherm Professionell and all accessories (all kind of cuffs and fixing aids) is safe.

Based on this confirmation it is expected, that the product will not cause cytotoxic effects or local skin irritation or sensitisation by intended usage.

The housing and handles of the units are made of the plastic materials ABS (housing), the material PP (handles) and PUR (cuffs).

The materials used don't contain Latex or PVC.

They don't contain phthalates (DEHP), or raw materials containing or derived from bisphenol A (BPA) or nano-material.

The packaging material also doesn't contain Latex, PVC, DEHP, BPA or nano-material.

Biocompatibility is ensured by tests according valid Biocompatibility standards of ISO 10993

Eisenharz, 06.10.2021



i.V. Christian Stegmann
Technical Director

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