KÖSEMED®
MEDICAL ORTHOPEDIC PRODUCTS

EC DECLARATION OF CONFORMITY

Manufacturer	:	**KÖSEMED ORTOPEDİ SAN. VE TİC. İTH. İHR. A.Ş.**
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E-mail	:	kosemed@kosemed.com
Web Address	:	www.kosemed.com
Product Brand	:	KÖSEMED
Product Group	:	"Hot&Cold Compress" (See attached product list below)
Classification	:	Class I Other (non-sterile product with no measuring function)
Assessment Route	:	Medical Device Regulation (MDR 2017/745) Annex IV Declaration of Conformity (Annex II & III)
Classification Rule	:	Medical Device Directive (MDR 2017/745) Annex VIII - Rule 1
GMDN Code	:	37240 (Hot/cold therapy pack, reusable)
Intended Use	:	A non-sterile device intended to be applied with or without pressure to the body surface (i.e., non-invasively) to provide heat and/or cold therapy for the skin and/or underlying tissues in the treatment of musculoskeletal pain and discomfort (e.g., from sports injuries or rheumatism). It consists of a compact envelope filled with a thermally-retentive gel that can be heated and/or cooled. This is a reusable device.

We LUXOR SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş. hereby declare that above mentioned product group which is given attached to this declaration as a detailed list conforms with the basic safety and performance requirements of the Medical Device Regulation (MDR 2017/745) and the following harmonized standard requirements including common specifications; these products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves; this EC declaration of conformity was written according to Medical Device Regulation (MDR 2017/745) Annex IV under our sole responsibility; all supporting technical documents of conformity to Medical Device Regulation Annex II & III and quality management system documentation conducted according to Annex IX of the regulation is retained under the premises of the manufacturer.

PRODUCT LIST:

PRODUCT NAME	MODEL /REF. NO	UDI-DI (BARCODE) NO
Hot & cold Pack / Thermojel S (13X13)	LC1610-01	8698758944381
Hot & cold Pack / Thermojel M (13X26)	LC1610-02	8698758944398
Hot & cold Pack / Thermojel L (26X37)	LC1610-03	8698758944404

Standards :

EN ISO 13485	EN ISO 14971	EN ISO 10993-1
MEDDEV 2.7/1 rev. 4	EN ISO 15223-1	EN ISO 9001
MEDDEV 2.12-1 rev. 8	EN ISO 20417	EN ISO 14001

Place of Issue : İzmir/ TÜRKİYE

Date of Issue : 16.09.2026

Authorized Person : Fehmi KÖSE

Authorized Title : General Manager

Approval (Stamp & Signature) :

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