

EU DECLARATION OF CONFORMITY

MANUFACTURER : KENMAK HASTANE MALZEMELERİ VE ELEKTROSTATİK BOYA SAN. TİC. A.Ş.

ADDRESS : SARNIC YOLU NO:23 GAZİEMİR İZMİR

PHONE : +90 232 274 17 17

E-MAIL : kenmak@kenmak.com.tr

WEBSITE: : www.kenmak.com.tr

EUDAMED SRN : TR-MF-000016184

AUTHORIZED REPRESENTATIVE : HUMAN CARE HC AB

AUTH. REP. ADDRESS : Årstaängsvägen 21B 117 43, Stockholm / SWEDEN

PRODUCT PHOTO	SEE LIST OF PRODUCTS
PRODUCT NAME	SEE LIST OF PRODUCTS
PRODUCT CODE	SEE LIST OF PRODUCTS
BASIC UDI-DI	SEE LIST OF PRODUCTS
CLASS	Class I - Other
SPECIFICATIONS	ISO 13485:2016, ISO 9001:2015, ISO 14971:2019, ISO 20417, TS 4271, TS 4510, TS 6607, TS EN 60601-2-52, ISO 15223-1:2016, MEDDEV 2.12.1 REV.08, MEDDEV 2.7.1 REV.04, MEDDEV 2.12.2 REV.02, NBOG 2010-1
DIRECTIVE	:2017/745
CONFORMITY ASSESSMENT	:2017/745 ANNEX IX

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF KENMAK HASTANE MALZEMELERİ VE ELEKTROSTATİK BOYA SAN. TİC. A.Ş.. WE DECLARE THAT THE ABOVE MEDICAL DEVICE(S) FOLLOW THE REGULATION (EU) MDR 2017/745 FOR MEDICAL DEVICES. THIS STATEMENT IS SUPPORTED BY ISO 13485 QUALITY SYSTEM APPROVAL BY WQR INTERNATIONAL CERTIFICATION LTD.. ALL SUPPORTING DOCUMENTS ARE STORED AT THE MANUFACTURER'S FACILITIES.

PLACE, DATE:

İZMİR, 29.07.2022

SIGNATURE:

SONAT K.KALKAN ARPAT

CEO

Kenmak
HASTANE MALZEMELERİ VE ELEKTROSTATİK
BOYA SANAYİ TİCARET ANONİM ŞİRKETİ
Dokuz Eylül Mh. Sarnic Yolu No:23 Gazimir - İZMİR
Tel:0232 274 17 17 / 0232 274 67 77
Mersis No:0810000345900001
Gazimir Yö. 544 062 7459

LIST OF PRODUCTS

PRODUCT PHOTO (APPLICABLE)	PRODUCT NAME	BASIC UDI-DI	REFERENCE NUMBER
 A hydraulic trauma stretcher with a blue padded surface, silver metal frame, and four wheels. A small label 'K034/T' is visible in the bottom left corner of the image.	HYDRAULIC TRAUMA STRETCHER (EPOXY POPWDERED)	869759512K034TKK	K034/T
 A black foldable wheelchair with a black seat, backrest, and large rear wheels. It has a small front wheel and a footrest.	FOLDABLE WHEEL- CHAIR	869759512K001MS	K001/14