



EU DECLARATION OF CONFORMITY

MANUFACTURER : KENMAK HASTANE MALZEMELERİ VE ELEKTROSTATİK BOYA SAN. TİC. A.S.
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| | |
|-----------------------|---|
| PRODUCT NAME | SEE LIST OF PRODUCTS |
| PRODUCT CODE | 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 |
| Place of Issue | :Izmir/Turkiye |


THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF KENMAK HASTANE MALZEMELERİ VE ELEKTROSTATİK BOYA SAN. TİC. A.S.. 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.

Date of Issue: 02.01.2023
EXPIRY DATE: 02.01.2028

SIGNATURE:
SONAT K.KALKAN ARPAT
CEO

Kenmak
HASTANE MALZEMELERİ VE ELEKTROSTATİK
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Tel:0232 274 17 17 / 0232 274 67 77
Mersis No: 35010100000000000001
Gaziemir V.D. 544 062 7459

LIST OF PRODUCTS

| PRODUCT PHOTO (APPLICABLE) | REFERENCE NUMBER | BASIC UDI-DI | PRODUCT NAME |
|---|-----------------------------|---------------------|-----------------------------------|
|  | K073 / M | 869759512K073MKN | METAL MEDICINE STORAGE CABINET |