

EU Medical Device Regulation 2017/745
Declaration of Conformity

Manufacturer Name	DENTAŞ KAĞIT SANAYİ A.Ş.
Manufacturer Address	Organize Sanayi Bölgesi 1. Kısım, Nevzat Kuru Cd. No:15, 20330 Honaz/Denizli
Manufacturer Individual Identity No.	TR-MF-000037204
If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address	-
Product group	Paper Kidney Tray Paper Bedpan Liner
Name of the product	1001942 Kidney Tray 1001905 Kidney Tray 1001903 Bedpan
Descriptive Information and Explanations of the Product	Presented in the attached list.
Conformity Assessment Procedure (Additions executed in the product evaluation are marked)	☒ ANNEX-IV (ANNEX II & III) Declaration of Conformity ☐ ANNEX-IX (ANNEX I & III) Quality Management System ☐ ANNEX-IX (ANNEX II) Technical Documentation Evaluation ☐ ANNEX-X Type Examination ☐ ANNEX-XI (SECTION A) Production Quality Assurance ☐ ANNEX-XI (SECTION B) Product Verification
Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies	ISO 13485:2016 EN ISO 13485:2016/A11:2021 ISO 9001:2015 ISO 14971:2019 ISO 24971:2020 ISO 15223-1:2021 ISO 10993-1 2017/745 IEC 62366-1:2015 ISO 10993-10 ISO 20417:2021 MEDDEV 2.12-1 rev 8 MEDDEV. 2.7.1 Rev.4 MEDDEV 2.4.1 Rev. 9 MDCG 2021-24 MDCG 2020-13 MDCG 2020-7 MDCG 2020-5 MDCG 2019-15 Rev.1 MDCG 2021-19 MDCG 2018-1 Rev.4 MDCG 2018-6 MDCG 2021-1 Rev.1 MDCG 2021-12 EN 13795-1 MDCG 2021-1 PAS29:1999

As **DENTAŞ KAĞIT SANAYİ A.Ş.** manufacturer, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices. The declaration of conformity has been prepared in accordance with Annex IV of MDR 2017/745.

CENTRAL

Organize Sanayi Bölgesi 1. Kısım
 Nevzat Kuru Caddesi No: 15
 TR-20330 Honaz - DENİZLİ - TURKEY
 Tel: +90 258 269 2100 Fax: +90 258 269 2710

BRANCH

Erenler OSB Mahallesi
 Cumhuriyet Bulvarı No: 4
 TR-68220 Taşpınar - AKSARAY - TURKEY
 Tel: +90 382 266 2700



Tax No: Saraylar V.D. 292 002 7559
 Trade Register No.: 918-Honaz

www.dentaskagit.com.tr

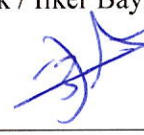
info@dentaskagit.com.tr

Dentaş Paper Industry Inc. is a subsidiary of ABALIOĞLU



DENTAŞ
KAĞIT SANAYİ A.Ş.

In accordance with the classification provisions by rule 1 of EU Regulation 2017/745 Annex VIII our products are classifieds Class I Medical Devices. (Please see Annex.1)

Signature Date and Place	:	29.02.2024 / Denizli Turkey
Signed by / Signature	:	Yüksel Zeybek / İlker Bayramoğlu   DENTAŞ KAĞIT SANAYİ A.Ş. Saraylar V.D.: 292 002 7559 Organize Sanayi Bölgesi 1. Kısım Nevzat Kuru Cad. No: 15 TR-20330 Honaz / DENİZLİ
Mission	:	Sales Manager / Denizli Factory Manager
Person Responsible for Regulation Compliance / Signature under Article 15 of 2017/745 MDR	:	Tuğba Kutlu Bodur 

CENTRAL

Organize Sanayi Bölgesi 1. Kısım
Nevzat Kuru Caddesi No: 15
TR-20330 Honaz - DENİZLİ - TURKEY
Tel: +90 258 269 2100 Fax: +90 258 269 2710

BRANCH

Erenler OSB Mahallesi
Cumhuriyet Bulvarı No: 4
TR-68220 Taşpınar - AKSARAY - TURKEY
Tel: +90 382 266 2700



Tax No: Saraylar V.D. 292 002 7559
Trade Register No. : 918-Honaz

www.dentaskagit.com.tr

info@dentaskagit.com.tr

Dentaş Paper Industry Inc. is a subsidiary of ABALIOĞLL



DENTAŞ
KAĞIT SANAYİ A.Ş.

ANNEX.1

This EU Declaration of Conformity covers ONLY products with the following catalog/reference numbers:

Catalogue/Reference Number	Product Name / Description	Intended Use	GMDN Code	EMDN Code	Class/ Classification Rule	Basic UDI-DI
1001942	Kidney Tray	Disposable kidney vial suitable for clinical use	42891-Dish, general purpose, disposable	V0402	Class-I / Rule 1	86842252372KIDNEYJ5
1001905	Kidney Tray	Disposable kidney vial suitable for clinical use	42891-Dish, general purpose, disposable	V0402	Class-I / Rule 1	86842252372KIDNEYJ5
1001903	Bedpan	Disposable kidney vial suitable for clinical use	42891-Dish, general purpose, disposable	V0812	Class-I / Rule 1	86842252372BEDPANCC

CENTRAL

Organize Sanayi Bölgesi 1. Kısım
Nevzat Kuru Caddesi No: 15
TR-20330 Honaz - DENİZLİ - TÜRKİY
Tel: +90 258 269 2100 Fax: +90 258 269 2710

BRANCH

Erenler OSB Mahallesi
Cumhuriyet Bulvarı No: 4
TR-68220 Taşpınar - AKSARAY - TÜRKİY
Tel: +90 382 266 2700



Tax No: Saraylar V.D. 292 002 7559
Trade Register No.: 918-Honaz

www.dentaskagit.com.tr
info@dentaskagit.com.tr

Dentaş Paper Industry Inc. is a subsidiary of ABALIOGLU