



EU DECLARATION OF CONFORMITY

COMPANY NAME : HEDEF İŞİTME CİHAZLARI VE TIBBİ CİH. İTH. İHR. SAN. TİC. LTD. ŞTİ.

ADRESS : PİRİ REİS DİSTRİCT. 2059 STREET. NO:5/1 MEGA TOWER
REZİDANCE ESENYURT / İSTANBUL/TURKEY

We are the manufacturer of the devices listed below and the devices with Medical Devices Regulation.

We declare that it is compliant with (EU) 2017/745 (MDR) and meets all relevant requirements within the MDR.

Classification : Medical Device Directive (EU) 2017/745, Class I according to the rules

This declaration of conformity has been created under the sole responsibility of the manufacturer.

Medical Device Regulation Conformity Assessment Procedure: Annex IV, Declaration of Conformity

Annex II, Annex III

PRODUCT NAME	SIZE	MODEL, REF NO	UDI CODE
ADULT DIAPERS	SMALL	SER-737 44227	868234017573744227QN
	MEDIUM	SER-737 44226	868234017573744226QL
	LARGE	SER-737 44225	868234017573744225QJ
	X LARGE	SER-737 44229	868234017573744229QS

This declaration of conformity has been made under the sole responsibility of the manufacturer.

We herewith declare that the attached product list meet the provisions of the council Directive (EU)2017/745 for medical devices all supporting documentation is retained under the premises of the manufacturer.

Issue Date : 25.08.2021

GENERAL MANAGER

HEDEF İŞİTME CİH. VE TIBBİ CİH. İTH. İHR. SAN. TİC. LTD. ŞTİ.
Piri Reis Mah. 2059 Sok. Mega Tower Rezidans No:5
Esenyurt / İSTANBUL
V.D. : Esenyurt / No:161 042 4263