



EU DECLARATION OF CONFORMITY

We here by, the Manufacturer

As Sevinçler Sağlık Ürünleri; We declare that our products, defined in the Annex, offered to the market in our country, comply with the basic safety and health conditions in terms of design and type according to the 2017/745 Medical Device Regulation (MDR) and are manufactured in accordance with the basic conditions specified in 'ANNEX-1'. In the event of any changes made to the product in question that are not accepted by us, this declaration will lose its validity.

Manufacturer's Name/Trade Name:	SEVINÇLER SAĞLIK ÜRÜNLERİ SAN. Ve Tic. A.Ş.
Manufacturer's address:	5th Organized Industrial Zone 83557 street No:9 BAŞPINAR/GAZİANTEP/Türkiye
Medical device:	See attached Product List
Intended Use:	Incontinence gland that collects urine and feces for patients , Skin care and cleansing
Justification of risk classification, class	Class 1, Annex VIII, Rule 1 (MDR 2017/745)
Nomenclature code, type and term:	GMDN (11239)
Additional European directives/Laws applicable on the product	Medical Devices Regulation (MDR) 2017/745 ,
Standards applied:	TS EN ISO 13485
Individual identification number	2667269150832
Basic (UDI-ID) Number	868013120YHB0DT

Signed on behalf of SEVINÇLER HEALTH PRODUCT

LIST

8680131208128	GİGGLES BLADDER PED LARGE 10 PCS
8680131208142	GİGGLES BLADDER PED LARGE 20 PCS
8680131208135	GİGGLES BLADDER PED MEDIUM 10 PCS
8680131208159	GİGGLES BLADDER PED MEDIUM 20 PCS