

## EU DECLARATION OF CONFORMITY

### MANUFACTURER:

Corporate Name : NAUSICAA MEDICAL  
Single registration number (SRN) : FR-MF-000000955  
Head Office adress : ZA Pôle Actif-30660 GALLARGUES LE MONTUEUX-FRANCE

---

### NAUSICAA MEDICAL:

- certify that the UE declaration of conformity is issued under the sole of our responsibility as manufacturer
  - confirms that the following devices are in conformity with the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices.
- 

### DEVICE:

Basic UDI-DI : 37014294DR7N  
Product and trade name : SLIDE SHEETS ; SLIDE SHEETS WITH HANDLES  
Model : DGL ; DGL5 ; DTR ; DTR5  
Products codes :DGL-195-70/140-110/130-70/80-70/48-48-PF ; DGL5-195-70/140-110/130-70/48-48-PF ; DTR-195-70/140-110/130-70-PF ; DTR5-195-70/140-110/130-70-PF  
Intended purpose : medical devices for home care and living aids for disabled patients (bed textile devices)  
Risk class of the device (Annexe VIII) : Class I  
Harmonised standards used and in relation to which conformity is declared :  
EN ISO 14971 : 2012 Medical devices - Application of risk management to medical devices  
EN ISO 15223-1 : 2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 : General requirements

---

Place and date of the declaration  
Gallargues le Montueux, 30<sup>th</sup> March 2021

Clément CHAUZAT  
President

