



EU DECLARATION OF CONFORMITY
according to Regulation (EU) 2017/745

1. Manufacturer information:

- 1.1 Name: TECNOCLÍNIC SA
1.2 Address: Ctra. de Prats de Lluçanès, Km. 2,300
P.I. La Llanera. E-08208 Sabadell (Barcelona)

2. The undersigned states that this EU declaration of conformity is issued under the sole responsibility of Tecnoclínic SA.

3. Basic UDI-DI: 843657368BCONSTNG

4. Product information:

4.1 Product trade name and product code: Urine collection bags

Customer reference	Tecnoclínic code
28688	800160
28690	800161
28689	800162
28692	800163
28694	802220
28691	802221
28695	802222
28693	802223
28707	804257
28708	804258

4.2 Intended purpose: the product is denominated urine bag and its purpose is the collection of urine both on patients with urinary incontinence and patients that after a postoperative are lying in bed without the possibility of getting up for performing its urinary needs, for its further disposal.

5. Product risk class according to annex VIII, rule 1: class I non sterile.

6. Tecnoclínic SA is registered in EUDAMED with actor code ES-MF-000000632.

7. The undersigned declares that the products referred to in this statement are covered by the present declaration and they are in conformity with Regulation (EU) 2017/745.

Place: E- 08208 Sabadell (Barcelona)
Date: 26/07/21
Name: Mireia Cabal Urpina
Function: Legal Representative

TECNOCLINIC, S.A.
CTRA. PRATS, KM. 2,300 - Ap. 331
SABADELL (Barcelona)

Name: Conxita Estradé Muñoz
Function: QM & RRAA Responsible

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