- Declaration of Conformity -272-003-7.1-Urimed B'Bags **Non Sterile** 

B. Braun Medical SAS Continence Care & Urology - Regulatory

Affairs Lifective

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## EC 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:

Customer reference	Tecnoclínic code	Leading lot number
URIMED B'BAGS REF. 29415	800152	160307
URIMED B'BAGS REF. 29435	800153	160009
URIMED B'BAGS REF. 29416	800154	162512
URIMED B'BAGS REF. 29410	801124	161734
URIMED B'BAGS REF. 29430	801125	160039
URIMED B'BAGS REF. 29411	801126	To be assigned
URIMED B'BAGS REF. 29450	802194	160357
URIMED B'BAGS REF. 29451	802195	160398
URIMED B'BAGS REF. 29455	802196	160359
URIMED B'BAGS REF. 29451R	802204	160790
URIMED B'BAGS REF. 29452R	802208	160625
URIMED B'BAGS REF. 29510	804226	To be assigned

- 4.2 Intended purpose: 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.
- 5. Product risk class according to annex VIII: class I non sterile
- 6. Tecnoclinic SA is registered in EUDAMED with actor code ES-MF-000000632.
- 7. The undersigned declares that the product referred in this statement is covered by the present declaration of conformity with Regulation (EU) 2017/745.

Place:

E- 08208 Sabadell (Barcelona)

Date:

28/01/21

Name:

Albert Cabal Marqués

Function:

**General Director** 

**Effective**