

- Declaration of Conformity -272-003-7.1-Urimed B'Bags Sterile B. Braun Medical SAS
Continence Care & Urology - Regulatory

Affairs Effective

Document ID: RA-OMCCU-000142

Version: 1.0

Effective Date: 2021-06-29

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EC DECLARATION OF CONFORMITY (according to Directive 93/42/CE modified by 2007/47/CE)

TECNOCLÍNIC, S.A.

The undersigned, Mr. Albert Cabal Marqués, on behalf of the above mentioned company, of Ctra. de Prats de Lluçanès, Km. 2,300 – P.I. La Llanera - 08207 Sabadell (Barcelona) - Spain.

STATES / DECLARES:

That the sanitary product:

STERILE URINE COLLECTION BAGS:

TECNOCLÍNIC CODE	CLIENT REFERENCE
A0103	URIMED B'BAGS 29400
A0104	URIMED B'BAGS 29420
A0304	URIMED B'BAGS 29440

Falls into Class I sterile and complies with all the main requirements established in:

Annex I and Annex V of Royal Decree 1591/2009

Directive 93/42/EC modified by 2007/47/EC

in relation to regulations on Sanitary Products

applicable, which guarantee the absence of health risks and personal safety, provided that the products is used for the purposes intended, in addition to offering the qualities assigned to it.

This product is included in Notified Body number 0373, Istituto Superiore di Sanità.

Date: 25-11-2015 Albert Cabal Marqués General Director

Effective

Document No.: NA - Version: 1.0 - Document ID: RA-OMCCU-000142 Print Date: 2021-06-29 22:02 (CET)