



PROMOS S.p.A.
Frazione Villa Lempa
64010 Civitella del Tronto (TE)
Tel. 0861.919123 – Fax 0861.919119
www.promosspa.it – info@promosspa.it



CE Declaration of Conformity for Medical Devices – class I

the manufacturer

PROMOS S.p.A.

Frazione Civitella Villa Lempa, 64010 Civitella del Tronto (TE)

AFFIRMS

under its own exclusive responsibility
as manufacturer of the following device group:

BASIC UDI-DI	PROMOS CODE	DEVICE
803398667MBX4	PF0004	sputum container
803398667MAX2	PF0006	female urinal
803398667MAX2	PF0010	male urinal
803398667MBX4	PF0012	measuring jug 1L
803398667MBX4	PF0023	wash bowl 4L
803398667MBX4	PF0026	general purpose bowl 3L
803398667MBX4	PF0027	small basin 1,7L
803398667MAX2	PF0376	midi slipper pan
803398667MBX4	PF0377	kidney dish
803398667MAX2	PF0378	maxi slipper pan
803398667MBX4	PF0379	general purpose bowl
803398667MAX2	PF0384	bedpan 2L
803398667MAX2	PF0388	italian slipper pan
803398667SBXN	PF0001	general purpose small bowl support
803398667SAXL	PF0009	bedpan support with handle
803398667SBXN	PF0011	large bowl support
803398667SAXL	PF0014	italian slipper pan support
803398667SAXL	PF0017	maxi slipper pan support
803398667SAXL	PF0024	midi slipper pan support

intended for the containment and transport of liquids/organic fluids, water repellent, free of natural latex
that they comply to the

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

*Ref.: ANNEX VIII: applicable classification rule: I - duration of use: transient - non-invasive device
concerning medical devices*

and complies with the general safety and performance requirements (Annex I) and with the applicable technical standards, listed in the technical dossier. The Technical File containing the relevant documentation is drawn up in accordance with Annex II and is kept at the Manufacturer's premises and made available to the Competent Authorities. The Manufacturer has implemented and maintains a post-sales surveillance procedure in accordance with Annex III.

Civitella del Tronto, 01/12/2022

PROMOS S.p.A.

Il legale rappresentante
(Paolo Mattei)

Firma



Rev. 3 del 01/12/22