

# TECHNICAL DATA SHEET

## Biflexy™ Sodium bicarbonate bag for haemodialysis



### PRODUCT DESCRIPTION

The Biflexy™ bag is a single use, non-sterile device that may only be used with the Flexya™ dialysis machine. The device is available in three different sizes: 750g, 900g, 1300g. The Biflexy™ bag contains powdered sodium bicarbonate which the Flexya™ dialysis machine automatically dissolves in appropriately treated water, via the hospital's dialysis water filtration system and the H<sub>2</sub>Oclean™ ultrafilter equipped on the dialysis machine. This produces a basic, concentrated solution for the treatment. This concentrate can be used with an acid solution containing chlorides and other electrolytes, key components of the dialysis fluid used in hemodialysis treatment. The dialysis fluid re-establishes the patient's blood acid-base balance, with the passing of solutes to and from the blood through the dialyzer membrane.

### INTENDED USE

Disposable bag containing sodium bicarbonate powder for extemporaneous and continuous production of concentrated sodium bicarbonate solution for hemodialysis purposes. The Biflexy™ device should only be used with the Bellco Flexya™ machine.

### CODES AVAILABLE

Code	Name	Description	CND	GMDN
IB0700000	Biflexy™ 750g	750g bicarbonate powder bag	F040201	35849
IB0700001	Biflexy™ 900g	900g bicarbonate powder bag	F040201	35849
IB0700002	Biflexy™ 1300g	1300g bicarbonate powder bag	F040201	35849

### STERILIZATION METHOD AND VALIDITY

Non-sterile and non-pyrogenic.

Shelf life: 2 years.

## TECHNICAL CHARACTERISTICS

The technical characteristics of the Biflexy™ bag are reported below.

Components	Materials
Bag content	Sodium bicarbonate
Film	Polyamide/Polyethylene (PA/PE)
Connector	High density polyethylene (HDPE)

## PACKAGING

Model	Secondary packaging – Box		
	Box	Weight <sup>1</sup> (kg)	Pcs/ Box
Biflexy™ 750g	Avana colored Rippled Cardboard Dimensions: 340 x 238 x 169 mm	6.6	8
Biflexy™ 900g	Avana colored Rippled Cardboard Dimensions: 340 x 238 x 143 mm	5.9	6
Biflexy™ 1300g	Avana colored Rippled Cardboard Dimensions: 340 x 238 x 169 mm	7.1	5

<sup>1</sup> Box weight filled with products

## STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between 0 and +40 degrees Celsius.

Disposal: remove the sodium bicarbonate bag from its holder and dispose of it in accordance with the applicable national laws.

## BIOCOMPATIBILITY

Biocompatibility tests of the Biflexy™ bags have been performed according to ISO 10993-1 and related applicable standard series.