

## EC DECLARATION OF CONFORMITY

According to Annex V of the MDD Directive 93/42/EEC

(Production quality assurance – sterility aspects only)

Based on: rule 1 of annex IX of the MDD; Chapter III- Classification; Point 1. Non-invasive devices

BEDAL N.V.

Agoralaan Abis – 3590 Diepenbeek, Belgium

Certifies that following Medical Device(s):

GMDN code	Description	Product	Product reference	Classification
58301	Sterile, single use patch for the stabilization of catheters, tubing, and cables	Bedal air M Bedal picc/cvc Bedal pivc Bedal flex, epi/pnb Bedal flex XS Bedal air S Bedal flex S Bedal flex M	DP01 PC02 PV02 EP02 UN-FLEX-XS UN02 UN-FLEX-S UN-FLEX-M	I Sterile

is (are) manufactured by BEDAL N.V., Agoralaan Abis, 3590 Diepenbeek, Belgium

These products:

1. Comply with all Essential Requirements (Annex I) of the MDD Directive 93/42/EEC.
2. This compliance has been properly documented using a checklist created from Annex I of the MDD Directive 93/42/EEC, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality Management System) specific documents.
3. The device that is covered by present declaration is in conformity with the Directive 93/42/ECC and, if applicable, with any other relevant Union Legislation that provides for issuing of an EU Declaration of Conformity.
4. Comply with the following harmonised standards:
  - ISO 10993-1
  - ISO 11607-2
  - EN ISO 10993-5
  - ISO 11737-1
  - ISO 10993-10
  - ISO 11737-2
  - EN ISO 11137-1
  - EN ISO 13485
  - EN ISO 11137-2
  - ISO 14971
  - ISO 11607-1
  - EN ISO 15223-1
5. BEDAL N.V. has been assessed against the requirements of Annex V – certification of the aspects of Manufacture relating to Sterility of the Medical Device Directive 93/42/EC and conforms to the requirements for the product(s) listed above.

The initial certificate with number: **BE19/819943317** has been issued by SGS Notified Body: **1639** on **13 February 2019** and is *valid for all mentioned variant devices as from 12 November 2020 till 03 January 2024.*

6. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

This EC declaration of conformity is issued under the sole responsibility of the manufacturer.

Agoralaan Abis  
B-3590 Diepenbeek

Alexander Van Damme  
Chief Executive Officer Belgium BEDAL N.V.



Diepenbeek: April 7<sup>th</sup>, 2022

(Place and date issued)

(Name and signature as well as position of declarant)