Docusign Envelope ID: CEACD870-FDBE-45D6-B553-76A80854276E

bedal International



# EC DECLARATION OF CONFORMITY

## According to Annex IV of the EU MD Regulation 2017/745

Based on: rule 1 of annex VIII Classification rules of the MDR; Chapter III- Classification rules; Point 4.1 Non-invasive devices. Classification: class Is

BEDAL International NV
Agoralaan Abis – 3590 Diepenbeek, Belgium
Certifies that following Medical Device(s):

| Description | Product | Reference |
|---|---|---|
| Sterile, single use patch for the stabilization of catheters, tubing, and cables | FlexGRIP EPI/PNB 20-16 G | EP02 |
| | Bedal Flex XS | UN-FLEX-XS |
| | Bedal Flex S | UN-FLEX-S |
| | Bedal Flex M | UN-FLEX-M |
| | FlexGRIP Universal 5-11 Fr | UN511 |
| | FlexGRIP Universal 11-18 Fr | UN1118 |
| | FlexGRIP PICC 3-6 Fr | PICC36 |
| | FlexGRIP CVC 4.5-9 Fr with Horseshoe | CVC459HS |
| | FlexGRIP CVC 4.5-9 Fr without Horseshoe | CVC45900 |
| | FlexGRIP Jr. PIVC | PIVCJR |
| | FlexGRIP Jr. NEX | NEXJR |
| | FlexGRIP Jr. Universal 5-11 Fr | UNJR511 |
| | FlexGRIP Jr. PICC 2,7-5 Fr | PICCJR275 |
| | FlexGRIP Jr. CVC 3-6 Fr with Horseshoe | CVCJR36HS |
| | FlexGRIP Jr. CVC 3-6 Fr without Horseshoe | CVCJR3600 |
| | FlexGRIP Foley 11-18 Fr | FOL1118 |
| | FlexGRIP Universal 18-25 Fr | UN1825 |
| | FlexGRIP Alpha PICC/Midline | ALPHA00 |
| | FlexGRIP Alpha CVC/Arterial | ALPHASS |

**SRN**: BE-MF-000001242
**Basic UDI-DI**: 5430000258FlexGRIPSAF
**EMDN code**: V9099

is (are) manufactured by BEDAL International NV, Agoralaan Abis, 3590 Diepenbeek, Belgium

These products:

1. Comply with all General Safety and Performance Requirements (Annex I) of the EU MD Regulation 2017/745.
2. This compliance has been properly documented using a checklist created from Annex I of the EU MD Regulation 2017/745, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality Management System) specific documents (Annex II & Annex III).
3. The devices that are covered by present declaration are in conformity with the EU MDR 2017/745 and, if applicable, with any other relevant Union Legislation that provides for issuing of an EU Declaration of Conformity.
4. BEDAL International NV has been assessed against the requirements of Annex IX – certification of the aspects of Manufacture relating to Sterility of the EU MD Regulation 2017/745 and conforms to the requirements for the product(s) listed above. The initial certificate with number: ***BE24/00000301*** has been issued by SGS Notified Body: **1639** on **27/Nov/2024** and is *valid for all mentioned variant devices* **until 27/Nov/2029.** The certificate is effective as of the **1st of January 2025**.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

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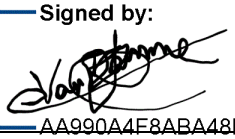
This EC declaration of conformity is issued under the sole responsibility of the manufacturer. A list of standards is available upon request.

Agoralaan Abis
B-3590 Diepenbeek
Belgium

Alexander Van Damme
Chief Executive Officer
BEDAL International NV

Signed by:

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Diepenbeek: December 11, 2024
(place and date issued)

(Name and signature as well as position of the declarant)