EU Declaration of Conformity

<PROTECTA>

Protecta for Toileting Universal Bedpan + Splashguard 02001
SafeBag Bedpan and Commode liner 03001

Document number: ID REC 2011 v2

Revision and date: 02 and 12.01.2026

Revision: 02

		Signature	Date
Prepared by	Name: Marieke Letteboer-Kamp Function: Business Development Manager	m Letteboer-Kamp	12.01.2026
Approved by	Name: Maarten Grootswagers Function: COO		12.01.2026

Revision history
- New document
- V2 updated legal entity and portfolio

Final conclusion

HYGIENIUS HEALTHCARE SOLUTIONS B.V. concludes that the Protecta and SafeBag Medical Devices (as listed below) with specific regards to its classification, performs clinically as intended, is safe and effective (for users and for the intended patient population) and is in compliance with the EU Medical Device Regulation (MDR) 2017/745.

These products will be produced in accordance with the relevant annexes of the MDR as confirmed in the EU Declaration of Conformity.

- Protecta for Toileting Universal Bedpan + Splashguard 02001
- SafeBag Bedpan and Commode liner 03001

EU DECLARATION OF CONFORMITY

This EU Declaration of Conformity states that the requirements specified in the EU Medical Device Regulation (MDR) 2017/745 have been fulfilled in relation to the devices covered in the technical documentation. Hygienius Healthcare will continuously update the EU declaration of conformity as required. This Declaration of Conformity conforms to Article 19 and Annex IV.

1. Issuer's name and address

HYGIENIUS HEALTHCARE SOLUTIONS B.V. SRN : NL-MF-000047130
De Corridor 7
3621 ZA Breukelen
The Netherlands

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, HYGIENIUS HEALTHCARE SOLUTIONS B.V. As these medical devices are Class 1 self-certified, HYGIENIUS HEALTHCARE SOLUTIONS B.V. does not engage the services of a notified body to perform a conformity assessment.

2. Object of the declaration

We hereby declare that the CE-marked medical devices, including the product group Protecta and SafeBag identified in the table below, are marketed in compliance with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. In accordance with the conformity assessment route for Class I products, the technical documentation set out in Annexes II and III of REGULATION (EU) 2017/745, has been drawn up.

Relevant Certificate	Product group	Classification & rule MDR Annex VIII
N/A – self certifying	Proteta	Class 1, Non-invasive Rule 1.
N/A – self certifying	SafeBag	Class 1, Non-invasive Rule 1.

The Protecta and SafeBag medical devices enables the toileting of bedridden patients in healthcare facilities. They are designed to be used by nursing staff in hospitals as well as nursing, care and revalidation facilities. The product is packaged in cases and the components are ready for use.

3. Product names and UDI DI codes

The Basic UDI-DI as referred to in Part C of Annex VI is a combination of the GS1 EAN barcodes listed below together with the batch identifier in the form of a unique LOT code (the production date in the format dd/mm/yy) printed on each product case.

- Protecta for Toileting Universal Bedpan & Splashguard. Product code 02001.
  Basic UDI DI: 87193269748PROTECTA9Q
  UDI DI : GS1 barcode 8719326974804 + batch specific LOT code.

- SafeBag Bedpan and Commode liner. Product code 03001.
  Basic Udi Di: 87193269748SAFEBAG7F
  UDI DI 6x20 pc : GS1 barcode 8719326974859 + batch specific LOT code.
  UDI DI 20 pc: GS1 barcode 8719326974866 + batch specific LOT code.

4. Harmonised standards used

The following harmonised standards have been used to demonstrate conformity to the General Safety and Performance Requirements:

Standard number and publication year	Description / title of Standard
ISO14971:2019	Application of risk management to medical devices
ISO13485:2016	Medical devices -- Quality management systems
ISO10993:2018	Biological evaluation of medical devices

5. Quality Management System

This declaration is based on the products fulfilling the obligations as defined in MDR article 52(7). This includes conformity to the General Safety and Performance Requirements stated in MDR 2017/745 Annex I and setting up a Technical dossier as defined in Annex II and III of MDR 2017/745.
The conformity of the Quality Management System has not been Certified as this is not an obligation for Medical Devices that are class I (with exception of class Is, Im or Ir).

6. Signature

This declaration of conformity is made on this date, January 12th, 2026 at the offices of HYGIENIUS HEALTHCARE SOLUTIONS B.V. located at De Corridor 7, 3621 ZA, Breukelen, The Netherlands. This declaration of conformity is signed by Maarten Grootswagers, COO, (holding the additional roles of Quality Manager and Person Responsible for Regulatory Compliance) on behalf of HYGIENIUS HEALTHCARE SOLUTIONS B.V.

Maarten Grootswagers
COO (Quality Manager & PRRC)

January 12th, 2026. Breukelen, The Netherlands