



DECLARATION OF CONFORMITY - MDR 2017/745
Brossard, Canada, September 2021

We, Hygie Canada inc., located at 9150 Leduc, Suite 204, Brossard, QC, Canada, J4Y 0E3, hereby declare under our sole responsibility that the product(s) listed in the Annex comply with the provisions of the regulation (EU) MDR 2017/745 of the European Parliament and of the Council on Medical Devices.

Manufacturer:

Hygie Canada Inc.
9150, Blvd. Leduc, Suite 204
Brossard (Québec) CANADA, J4Y 0E3

Product type:

Body fluid management systems: product/product family.

Intended use:

Hygie/Hy Industrie body fluid management systems are primarily designed for the containment, transport and elimination of potentially harmful pathogens (virus, bacteria) that are transmitted by body fluids. It protects the patients and the surrounding environment from cross-contamination or re-contamination.

Some of the Hygie/Hy Industrie body fluid management systems devices could be fitted with support accessories to improve their use. As such, these accessories are not to be considered as system or procedure pack as per Article 22 of the Regulation (EU) 2017/745 of the European Parliament.UDI:

UDI:

Hygie/Hy Industrie body fluid management systems are identified by UDI, whose prefix is: 10823853

Classification:

These products are classified as risk Class 1, as non-invasive devices under Annex VIII. They were previously qualified as Class I following Rule 1 of Annex IX of the Council Directive 93/42/EC.

These products have an auto-declaration and do not require a notified body.

Representative:



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Prinsessegracht 20
2514 AP The Hague
The Netherlands

SRN NL-AR-000000116

ISO 13485:

PECB has issued the ISO certificate: Annex stated on the certificate, renewed in April 2021.

Products*:

- ProHy21 Kit Bedpan/Hygie Bedpan ProKit - KT-PRO-HY21-B00
- ProHy21 Kit Vomit/Hygie Vomit ProKit - KT-PRO-HY21-VOO / KT-PRO-HY21-V01
- ProHy21 Kit Urinal/Hygie Urinal ProKit — KT-PRO-HY21-UL0
- Hy-SO Kit - Isolation HY-HYSO-000-006
- Bedpan Kit - I-KBJ04
- Vomit Kit - I-KVM06
- Urinal Kit - I-KUL04
- Hy21 Bedpan Support / Hygie Bedpan Support — BA-BASS-HY21-000
- Hy21 Bedpan Extender / Hygie Bedpan Extender — BA-BASS-HY21-SFO
- Hy21 Yellow Bedpan Support / Hygie Yellow Bedpan Support — BA-BASS-HY21-JAU
- Hy21 Vomit Support / Hygie Vomit Support — HY-SUPP-VOMO-000
- Hy21 Urinal Support / Hygie Urinal Support — HY-SUPP-UR13-000
- Hygienic Cover for Bedpan/Commode Chair - SA-HYGI-CLBI-000 / SA-HYGI-CLBI-E00 / SA-HYGI-CLBI-N00
- Hygienic Cover for Urinal support - SA-HYGI-URIO-000 / SA-HYGI-URIO-E00 / SA-HYGI-URIO-N00
- Hygienic Cover for Vomit support - SA-HYGI-VOMO-000/ SA-HYGI-VOMO-E00 / SA-HYGI-VOMO-N00
- Hygienic Cover for Pail - SA-HYGI-CLSB-000
- Hygienic Cover for Toilet - SA-HYGI-PCWC-000
- Hygienic Cover - Bedpan/Commode Chair — 1-EVB10
- Hygienic Cover - vomit — 1-EVM12
- Hygienic Cover - urinal — 1-EUR12
- GOVOM Graduated Vomit bags with absorbent pad — 1-PRBVI / SA-HYGI-GOVO-000





- Super absorbent pad – SA-TAMP-ABSO-020 / SA-TAMP-ABSO-N20 / SA-TAMP-ABSO-400
- Extra absorbent pad — SA-PADS-8X95-000
- Super absorbent powder — SA-SAPB-450G-012
- Super absorbent stick - SA-BAGA-COUR-000 / SA-BAGA-LONG-000
- Hygienic garbage bags — bedpan size SA-HYGI-BAG1-400
- Hygie Urinal Collection Bucket (bocal à diurèse) — HY-COCO-U24H-000
- Hygie Urinal Collection bucket liners — SA-HYGI-U24H-000
- Hygie Aluminum Commode Chair — CH-HYAL-R017-KTE
- Hygie Simplici-T Commode Chair – CH-HYCC-NHU0-000
- Hygie Wet Wash Gloves – 1-GLOV15
- Hygie Dry Glove – GA-SEC-01
- Go Pee Plus – Urinal bag with super absorbent pad – SA-HYGI-GOPE-300 / SA-HYGI-GOPE-400

*ProHy21, ProKits, Hygie, Hygienic Cover, Go Vom & Go Pee are all registered trademarks



Mr. Éric Tanguay
President
Hygie Canada Inc.

Hygie Canada Inc.
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Done in Brossard (Québec), CANADA

On February the 18th, 2022



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