Manufacturer:	Urgo Healthcare Products Co.,Ltd
Manufacturer Address:	154 Tiwanon Road, Moo 5, Tambol Bangkadee, Amphur Muang, Pathumthanee 12000, Thailand
Manufacturer's Single Registration Number (SRN)	TH-MF-000029677
Basic UDI-DI	8851401UHPTF0099Y
EMDN code	M050201– Extensible non-woven plasters
GMDN code	16866 – Dressing-fixation skin adhesive tape, non-silicone
Authorized Representative:	Compliance Management Solutions Europe Ltd.
Authorized Representative Address:	2 Bulgaria Str, 2850 Petrich, Bulgaria
Authorized Representative's Single Registration Number (SRN)	BG-AR-000020809

Hereby declares that the following device:

Device Name:	URGODERM
REF/Product code	URGODERM 5Mx10CM GLOBAL: 604681 URGODERM 5Mx5CM GLOBAL: 604682 URGODERM 10Mx5CM GLOBAL: 604683 URGODERM 10Mx10CM GLOBAL: 604685 URGODERM 10Mx5CM - FR/DE: 604737 URGODERM 10Mx10CM - FR/DE: 604738 URGODERM 10Mx15CM - FR/DE: 604739 URGODERM 10Mx20CM - FR/DE: 604731
Intended Purpose:	URGODERM is intended to fixing and maintaining of dressings and devices, especially on joint and anatomical relief areas.
Scope of Application:	All URGODERM devices launched after 9th December 2025
Classification:	Class I, Rule 1
Conformity Assessment Route:	Annex II, III
Common Specifications (CS):	N/A
Standards Applied	Appendix 1

Meet the relevant provisions of Regulation (EU) MDR 2017/745 for medical devices and is issued under the sole responsibility of Urgo Healthcare Products Co.,Ltd. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:	N/A
(EC) Certificate(s) No.	N/A
Start of CE-Marking:	December 2025

Signed for on behalf of Urgo Healthcare Products Co., Ltd, responsible for the issuance, maintenance, extension, suspension or withdrawal of this Declaration of Conformity.

Name	Position	Signature	Date
Wiyada KATTIYAKAS	QA & RA Manager		- 9 DEC 2025

Place of Issue: Pathumthanee, Thailand

Revision	Changes	Date
01	New issue	9th December 2025

APPENDIX 1: STANDARDS APPLIED

STANDARD	DESCRIPTION
GENERALITIES AND MANAGEMENT	
EN ISO 13485:2016 ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
REGULATION (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
PATIENT RISKS AND USEABILITY STANDARDS	
ISO 14971:2019 *EN ISO 14971:2019/A11:2021*	Medical Device - Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices. Guidance on the application of ISO 14971
EN 62366-1:2015/A1:2020	Medical devices. Part 1 : Application of usability engineering to medical devices
PRODUCTS/ MATERIAL TECHNICAL STANDARDS	
ISO 29862:2018 *EN ISO 29862:2019*	Self adhesive tapes — Determination of peel adhesion properties
European Pharmacopeia	European Pharmacopeia
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
ICH Q1A(R2):2003	Stability testing of new drug substances and products.
ICH Q1E:2003	Evaluation of stability data
EN 13726:2023	*Test methods for wound dressings - Aspects of absorption, moisture vapour transmission, waterproofness and extensibility*
LABELLING	
EN ISO 15223-1:2021 *ISO 15223-1:2021/AMD 1:2025*	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
TECHNICAL MANUFACTURE STANDARDS	
ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3 : test methods

ISO 2859-1/A1:2011	Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ASTM D4169:2024	Standard Practice for Performance Testing of Shipping Containers and Systems
MICROBIOLOGY	
ISO 11737-1:2018/Amd-1:2021 *EN ISO 11737-1:2018/A1:2021*	Sterilization of medical devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products
European Pharmacopoeia current edition - part 2.6.13	Microbiological examination of non-sterile products: test for specified micro-organisms
European Pharmacopoeia current edition - part 5.1.4	Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
BIOCOMPATIBILITY	
ISO 10993-1:2018 EN ISO 10993-1:2020	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021 EN ISO 10993-10:2023	Biological evaluation of medical devices Part 10: Tests for skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
ISO 10993-18:2020/ Amd 1:2022	Biological evaluation of medical devices. Part 18: Chemical characterization of medical device materials within a risk management process
CLINICAL EVALUATION AND POST-MARKETING SURVEILLANCE	
MEDDEV 2.7/1 rev.4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC AND 90/385/EEC
ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers
MEDDEV 2.12/1 rev. 8	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2 rev. 2	Guidelines on a Medical Devices - Post market clinical follow-up studies