EU Declaration of Conformity

Prepared in accordance with Annex IV of Regulation (EU) 2017/745

1. MANUFACTURER

Name: Links Medical Products, Inc.
Address: 23091 Mill Creek Drive, 2nd Floor
Laguna Hills, CA 92653
United States
SRN: US-MF-000021290

2. AUTHORIZED REPRESENTATIVE

Name: Cost Saving Solutions Europe Ltd
Address: Unit 35 Centre Block, Docklands Innovation Park
East Wall Road, Dublin D03 E086
Ireland
SRN: IE-AR-000016085

3. PRODUCT IDENTIFICATION

Device Name: Silent Knight® Pill Crusher

Catalogue Number: SK-0500-LMP

Basic UDI-DI: 851028001SKRH

UDI-DI: 00851028001568

UDI-PI: Lot / Batch controlled

Accessory Name: Silent Knight® Pouches

Catalogue Number: PC1000-LMP

Basic UDI-DI: 851028001SKRH

UDI-DI: 00851028001575

UDI-PI: Lot / Batch controlled

4. INTENDED PURPOSE

The Silent Knight® Pill Crusher is a manually operated mechanical device intended to reduce prescribed solid oral medication tablets into powder form in healthcare settings under professional supervision.

The Silent Knight® Pouches (PC1000) are accessories to a medical device in accordance with Article 2(2) of Regulation (EU) 2017/745 and are intended to contain medication during crushing to reduce contamination and medication loss.

5. CLASSIFICATION

Class I medical device – Annex VIII, Rule 1

PC1000 Pouch – Class I Accessory under Annex VIII, Rule 1

6. CONFORMITY ASSESSMENT ROUTE

The devices identified in this declaration are Class I, non-sterile, non-measuring medical devices and accessories.

Conformity assessment has been conducted in accordance with Article 52(7) and Annexes II, III, and IV of Regulation (EU) 2017/745.

7. STANDARDS APPLIED

The following harmonized standards and specifications have been applied, where applicable:

- ISO 14971:2019 – Medical devices – Application of risk management to medical devices
- EN ISO 15223-1:2021 – Symbols to be used with information supplied by the manufacturer
- EN ISO 20417:2021 – Information to be supplied by the manufacturer
- EN ISO 13485:2016 – Medical devices – Quality management systems

8. DECLARATION

Links Medical Products, Inc. hereby declares under its sole responsibility that the devices identified in this EU Declaration of Conformity comply with the applicable requirements of Regulation (EU) 2017/745 on medical devices.

Technical Documentation has been prepared and maintained in accordance with Annex II and Annex III of Regulation (EU) 2017/745.

The conformity assessment procedure for Class I non-sterile, non-measuring devices in accordance with Article 52(7) has been applied.

APPROVED BY (Sign/Date)	TITLE
Signed by Gary Chilson Gary Chilson | I approve this document 6/2/2026 | 12:34:49 PM PDT 6C98314704654FF998A52D6CCB29BBF7	QA/RA Manager

8. REVISION HISTORY

Rev.	Nature of changes	Distribution
01	New Document	Signed pdf in controlled folder
02	Corrected Basic UDIs, added details to section 6, updated standards, updated declaration, moved approval and revision history to end.	Protected pdf in controlled folder