# Declaration of Conformity

for Mucolyse

**Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices**

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

| | |
|---|---|
| **General Product Name:** | Mucolyse |
| **Legal Manufacturer: (Name on Label)** | Pro-Lab Diagnostics Inc.<br>20 Mural Street, Unit#4<br>Richmond Hill, Ontario<br>Canada L4B 1K3 |
| **SRN:** | CA-MF-000011305 |
| **Basic UDI-DI:** | 62842900100PU |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Intended Purpose:** | Sputum liquefying agent |
| **IVDR Classification:** | Class A [Rule 5 ] |
| **Notified Body:** | Not applicable for Class A |
| **CE Certificate:** | Not applicable for Class A |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. |
| **EU Authorised Representative SRN:** | MT-AR-000000234 |
| **IVDR Assessment Route:** | *Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.* |

**Name** Karim Hirji **Position** Vice President, Operations

**Signed** **Date** 2022-01-31 **Place** Pro-Lab Diagnostics Inc.
20 Mural Street, Unit#4
Richmond Hill, Ontario
Canada L4B 1K3

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

### Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

| Standard/CS/Document Name | Description |
|---|---|
| 2017/746 | Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices |
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019+A11:2021 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 15223-1:2021 | Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements |
| EN ISO 20417:2021 | Medical devices. Information to be supplied by the manufacturer |
| EN ISO 18113-1:2011 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements |

### Appendix II – Product Listing/Schedule

| Catalogue Number | Device Description | EMDN Code | UDI-DI |
|---|---|---|---|
| PL.701 | Mucolyse (100 mg) | W01019001 | 10628429001001 |
| PL.701 | Mucolyse (10 x 100 mg) | W01019001 | 20628429001008 |

## Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1.0 | M. Owen / L. Gin | 2020 02 03 | First issue |
| 2.0 | L. Gin | 2020 05 06 | GMDN code added |
| 3.0 | V.Vengadessin | 2022-01-31 | Updated for EU IVDR 2017/746 |