Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Mediplast Australia Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, on receipt of an application from Mediplast Australia Pty Ltd (the **Applicant**) have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraph (**A**) below for the devices identified in paragraph (**B**):

(A) *Increase secretion mobilisation in the airways in cases of mucous consolidation (e.g. cystic fibrosis, acute viral bronchiolitis, bronchitis) by osmotic effects*, used in the Instructions for Use document (**IFU**) for the devices identified in paragraph (**B**) when the IFU is published on the Applicant's website.

(B) devices marketed as "Mucoclear 3%" and "Mucoclear 6%" under the following entries in the Australian Register of Therapeutic Goods

- Mediplast Australia Pty Ltd – Inhalation-therapy sterile saline solution, hypertonic (ARTG348614), and
- Mediplast Australia Pty Ltd – Inhalation-therapy sterile saline solution, hypertonic (ARTG 348610).

Dated this 17th day of February 2021

Signed electronically

Rowena Love
Delegate of the Secretary to the Department of Health
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch