Australian Government

Department of Health
Therapeutic Goods Administration

Application ID: DV-2020-CR-36137-1
TGA Reference: E21-208609

Bracton Industries NSW Pty Ltd
PO Box 1348
DEE WHY NSW 2099

Email: ben@bracton.com

Attention: Ben Hudghton

Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG Listing for Other Therapeutic Goods

ARTG	GMDN code and term	Therapeutic Type
343510	9950 Disinfectant, hospital grade	Other Therapeutic Good - Listed disinfectant

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3) of the Act following your request on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or efficacy of the kind of therapeutic goods for the purposes for which these goods are intended to be used.

Therefore, I have accepted the following information:

- SARS-CoV-2 (COVID-19): Contact time - 30 seconds.

Date of amendment: 12 March 2021

Relevant Legislation:

- *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2020C00028); and Unincorporated Amendments: *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* (C2018A00007) (https://www.legislation.gov.au/Series/C2004A03952);
- Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019. (https://www.legislation.gov.au/Details/F2019L00482)

Sponsors' ongoing regulatory responsibilities
Australian sponsors of therapeutic goods have ongoing regulatory responsibilities for the goods they supply to the Australian market.

The continued listing of the goods of the kind in the ARTG is subject to payment of annual charges.

Ongoing monitoring of quality, safety and efficacy
Therapeutic goods on the ARTG are subject to ongoing monitoring of their quality, safety and efficacy. At any time, the ARTG entry may be selected for a review to verify compliance of the goods with the regulatory requirements.

Review of the decision under section 60 of the Act
Should you wish to seek a review of my decision to vary the ARTG entry, your rights of review are outlined in Attachment A to this letter.

Yours sincerely

Signed and authorised by
Kerrie Muir
Delegate of the Secretary for the purposes of section 9D of the Act
Medical Devices Branch
17 March 2021