



B. Braun Medical Industries Sdn. Bhd
Company Reg: 197401001922 (19051-M)

Phase 2, Bayan Lepas Free Industrial Zone
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10810 Penang, Malaysia

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National Pharmaceutical Regulatory Agency
Ministry of Health of Malaysia

Your Reference

Our Reference
OQP/LOD/2021/029

Tel (604) 632 4526

2021-09-02

Letter of Justification

We, the manufacturer,

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone
11900 Bayan Lepas
Pulau Pinang, Malaysia

hereby confirm that there is constraint in printing the manufacturing date on the ampoule label of the miniplasco container in 10ml and 20ml pack sizes of B. Braun 0.9% Sodium Chloride Injection B.P. (MAL19920250AZ).

B. Braun 0.9% Sodium Chloride Injection B.P. 10ml and 20ml (MAL19920250AZ) is manufactured in BMI site with an old machine installed that can only cater for front label with dimension 2 x 3.1 cm. Due to the limited space, the printing of manufacturing date on the Miniplasco label is not possible.

We are at your disposal should you have any further queries.

Yours faithfully,
For and on behalf of
B. BRAUN MEDICAL INDUSTRIES SDN. BHD.

Lai Pei Thong
Qualified Person (Pharma)

Vignesvaran Subramaniam
Sr. Manager – Quality Management (Pharma)