



Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 088308 0025 Rev. 00

Manufacturer: HARPS Investment Asia Pte. Ltd.

> #08-10A Marina One West Tower 9 Straits View

Singapore 018937 **SINGAPORE**

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 088308 0018 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.

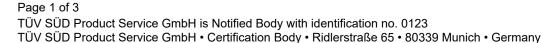
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 088308 0025 Rev. 00

Report No.: 713334421

Valid until: 2024-05-26

Christoph Dicks

Issue Date: 2024-04-22 Head of Certification/Notified Body







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No. GCQ 088308 0025 Rev. 00

Product Category(ies): Sterile surgical gloves

Description of Change:

Change of Headquarter address from: Semperit Investments Asia Pte. Ltd.

8 Jurong Town Hall Road, #29-03 to 06 The JTC Summit

609434 Singapore, SINGAPORE

to:

HARPS Investment Asia Pte. Ltd. #08-10A Marina One West Tower

9 Straits View

Singapore 018937, SINGAPORE

Change of facility address from: Sempermed Europe GmbH

Am Belvedere 10

1100 Vienna, AUSTRIA

HARPS Europe GmbH Wiedner Guertel 9-13 1100 Vienna, AUSTRIA

Change of EC-Representative address from: Semperit Technische Produkte Gesellschaft mbH Triester Bundesstraße 26 2632 Wimpassing, AUSTRIA

HARPS Europe GmbH Wiedner Guertel 9-13 1100 Vienna, AUSTRIA





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Description of Change:

De-Listing of surgical gloves product families (not covered by certificate anymore) as follows:

| Article Number | Article description | Last sold in | Last production in |
|----------------|-------------------------|------------------------------------|---|
| 826054524 | Euroderm powder 5,5 | 2020-12 (Shelf life 5 years) | 2020-12 (Shelf life 5 years) |
| 826054604 | Euroderm powder 6 | | |
| 826054624 | Euroderm powder 6,5 | | |
| 826054704 | Euroderm powder 7 | | |
| 826054724 | Euroderm powder 7,5 | | |
| 826054804 | Euroderm powder 8 | | |
| 826054824 | Euroderm powder 8,5 | | |
| 826054904 | Euroderm powder 9 | | |
| 821751521 | Sempermed® Senso PF 5.5 | 2020-12 (Shelf life 3 years) | 2020-12 (Shelf life 3 years) |
| 821751601 | Sempermed® Senso PF 6 | | |
| 821751621 | Sempermed® Senso PF 6.5 | | |
| 821751701 | Sempermed® Senso PF 7 | | |
| 821751721 | Sempermed® Senso PF 7.5 | | |
| 821751801 | Sempermed® Senso PF 8 | | |
| 821751821 | Sempermed® Senso PF 8.5 | | |
| 821751901 | Sempermed® Senso PF 9 | | |
| 3000012109 | Sempermed Latex PP 5,5 | Product was never sold | An order was never placed for this product |
| 3000012110 | Sempermed Latex PP 6 | | |
| 3000012111 | Sempermed Latex PP 6,5 | | |
| 3000012112 | Sempermed Latex PP 7 | | |
| 3000012113 | Sempermed Latex PP 7,5 | | |
| 3000012114 | Sempermed Latex PP 8 | | |
| 3000012115 | Sempermed Latex PP 8,5 | | |
| 3000012116 | Sempermed Latex PP 9 | | |