



Product Service

## 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](http://www.tuvsud.com/ps-cert?q=cert:GCQ_088308_0025_Rev.00)

**Report No.:** 713334421

**Valid until:** 2024-05-26

Christoph Dicks  
Head of Certification/Notified Body

**Issue Date:** 2024-04-22

## Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

**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  
to:  
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  
to:  
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		
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		