

FIELD SAFETY NOTICE



Moving Health Forward

Combi Commode/Shower Chair, attendant operated

Affected Devices:

Description: Combi Commode/Shower Chair, attendant operated

Article Numbers: 201904314, 201903314, 201911314



Date: 21 April 2022

Attention: All Customers and End-users

Reason: In response to a request by the Medical Products Agency (MPA)

Lot Numbers: Devices sold between 26 May 2021 to 31 March 2022, as shown below:

REF 201904314	REF 21903314	REF 201911314
2021-02-B	2021-04-B	2021-04-B
2021-05-B	2021-06-B	2021-05-B
2021-06-B	2021-07-B	2021-09-B
2021-09-B	2021-09-B	2021-10-B
2021-10-B	2022-01-B	
2021-12-B	2022-02-B	
2022-01-B	2022-03-B	
2022-02-B		
2022-03-B		
2022-04-B		

Direct Healthcare Group Sverige AB
Torshamnsgatan 35, 164 40, Kista, Sweden

T: +46 (0) 8 557 62 200 info.se@directhealthcaregroup.com
VAT Registration Number: SE556245585601

www.dhg-healthcare.com

FIELD SAFETY NOTICE

Dear Valued Customer:

The purpose of this letter is to advise you that Direct Healthcare Group Sverige AB (DHG) is executing a Field Safety Notice for the Combi Commode/Shower Chair, assistant operated. This Field Safety Notice describes below the action advised to be taken by you.

- Contact DHG to request refund or replacement of your Combi Commode/Shower Chair, assistant operated.

Description of Issue - The MPA has requested that these devices sold between 26 May 2021 and 31 March 2022 are removed from the field. This recall is due to a regulatory issue and there is no patient risk from the devices already in use.

Actions to be taken by the user of the device - Contact your DHG representative or the DHG Sverige AB Head Office on +46 (0) 8 557 62 200 to arrange a refund or replacement for your Combi Commode/Shower Chair, attendant operated.

Transmission of this Field Safety Notice - Please assure within your organisation that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them also, informing them of the below mentioned contact person.

Please maintain awareness on this notice for an appropriate period to ensure effectiveness of the above action.

A copy of this Field Safety Notice has been provided to the MPA.

Confirmation - Please complete and return the attached Confirmation Form and table (see Appendix) via email to quality.se@directhealthcaregroup.com to confirm that the above actions have been taken.

Contact reference person - For questions regarding this Field Safety Notice, please contact:

Andrew McCartney (Chief Commercial Officer)
Direct Healthcare Group Sverige AB
Torshamnsgatan 35, 164 40, Kista, Sweden
Tel: +46 (0) 8 557 62 200
Email: Andrew.mccartney@directhealthcaregroup.com

Thank you for your cooperation in this matter. Direct Healthcare Group Sverige AB is committed to providing quality products and service to its customers and we apologise for any inconvenience this situation may have caused.

Yours faithfully,



Jo Campbell
QARA Director



Andrew McCartney
Chief Commercial Officer

Enclosures:

Appendix: [Confirmation Form and Table](#)

Appendix

Field Safety Notice – Confirmation Form

Product Name: **Combi Commode/Shower Chair, attendant operated**
MPA Reference Number: **Dnr 6.6.3-2022-2504**
Date: **21 April 2022**
Type of Action: **Product Recall**

Hospital / Facility Name	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	Date:

I have read and understood the contents of this Field Safety Notice and confirmed the status of affected Combi Commode/Shower Chair(s) on the attached confirmation form.

Please return by **30 June 2022** to:

Direct Healthcare Group Sverige AB
Torshamnsgatan 35, 164 40, Kista, Sweden

Email: quality.se@directhealthcaregroup.com

