

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13

Circular No: **MSD/Q/S/2026/8**

26 -05-2026

To :

DDG/NHSL – Colombo,
DDG/NH – Kandy,
DDG/NH – Galle,
All Provincial Directors of Health Services,
All Regional Directors of Health Services,
All Directors of Teaching Hospitals,
All Directors of Specialized Campaigns,
Director, N.I.H.S Kalutara,
All MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry.

REPORT ON FAILING SAMPLE – Colostomy Appliance Set Complete, comprising; 02 Nos. base plates 50mm diameter (approximately) with support flange, adjustable belt and 10 Nos . drainable bags with 2 Nos. clamp

MSD Order List No : 2025/SPC/N/R/S/00034
2023/SPC/N/R/S/00389

PA Order No: DHS/M/SA/WW/01/020DC/25
DHS/RS/RQ/02/60KC/2023

Re-above, details of the letter NMRA/MD/QF/02/2025 dated 15th May 2026 received from CEO/NMRA are circulated herewith for your information and necessary action, please (NMRA correspondence was received by MSD on 22.05.2026, and the SWASTHA System notification was shared on the same day)

1.1) Name of the product/Item : **Colostomy Appliance Set Complete, comprising; 02 Nos. base plates 50mm diameter (approximately) with support flange, adjustable belt and 10 Nos. drainable bags with 2 Nos. clamp**

Colostomy Appliance Set Complete (BAO-Health)

SR : **12200203**

1.2) Manufacturer : BAO Health Medical Instruments Co., Ltd, 2nd Floor of 8-2 Building, Gaoqiao Industrial Zone, Tongxiang City, Zhejiang, 314515, P.R. China

1.3) Batch Details :

Batch No	Date of Manufacture	Date of Expiry
DD202508-1301	2025 September	2028 September
DD202311-19	2024 January	2027 January
DD202405-01	2024 June	2027 June

1.4) Reference of NMRA : To the decision of the 104th **Medical Device Evaluation Committee (MDEC)**, which recommended to withdraw the above batches

1.5) Nature of Defect : Poor adhesion and skin irritation, reducing colostomy bag usage duration

2. CEO-NMRA Instruction : **To withdraw the above mentioned batches from use Immediately**


3. Considering above facts, you are requested the following

3.1) **To withdraw the above mentioned batches (as detailed 1.1-1.3 above) from use immediately**

4. Please note: It would be your responsibility, in addition to point 3,
- 4.1) To follow the instructions given by Secretary of Health, under the circular No: 01/2021 dated 08.12.2021.
5. 5.1) Please bring the contents of this circular to all concerned in your Province/ Region/ Institution.
- 5.2) Please Note: It is the responsibility of all RDHS to ensure that the copies of this circular is circulated among all the heads of the institutions under your preview.

6. Previous Circulars

Circular No	Batch	Decision
MSD/Q/S/2025/11	DD202405-01	Withhold
MSD/Q/S/2025/18	DD202311-19	Withhold
MSD/Q/S/2026/5	DD202508-1301	Withhold


Dr. DEDUNU DIAS
 Director - (Acting)
 Medical Supplies Division
 Rev. Baddegama Wimalawansa Thero Mw,
 Colombo 10.
 Director,
 Medical Supplies Division,

Cc:

- | | | |
|---|---|--------------------|
| 1. Auditor General - f.i. | 2.DGHS-f.i. | 3. DDG(M/S) - f.i. |
| 4. Chairman/SPC – f.i. & n.a. | | |
| 5.CEO/NMRA – f.i. | 6. DD/MSD - f.i. & n.a | |
| 7. D/NMQAL – f.i. | | |
| 8. Chief Internal Auditor/ MOH-f.i. | 9.D/(Stock Verific.)/MOH - f.i. | |
| 10. Chief Accountant (Finance) / MSD – To make arrangements to recover the relevant charges | | |
| 11. Chief Accountant (Supply) / MSD – To make arrangements to recover the relevant charges | | |
| 12. AD/ICT Unit – To publish in MSD web site | | |
| 13. AD(S)/MSD – f.i. & n.a. | | |
| 14. AD (M&C) – f.i. | | |
| 15. AD (Stores)/MSD - f.i. | 16. AD(Dispatch)/MSD – f.i. | |
| 17. Secretary / MDEC- f.i. | | |
| 18. All DP/DPDHS - f.i. & n.a. | 19. SP / MSD - f.i. | |
| 20. HSCO (S) - f.i. & n.a. | | |
| 21. SCO (S/WH 12) – f.i. & n.a. | | |
| 22. SCO (D/WH 12)- f.i & n.a. | 23.MSA-WH (12)/MSD - f.i. & n.a. | |
| 24. MO (Technical unit)/MOH- f.i & n.a. | 25. H/Destruction Unit (MSD) - f.i & n.a. | |