

My No: MSD/SCU(S)/Cir/2025  
Medical Supplies Division,  
357, Ven. Baddegama Wimalawansa Thero Mawatha,  
Colombo 10.  
Tel: (011)2694114/13  
05-2026

Circular No: **MSD/Q/S/2026/7**

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 – Drug Eluting Coronary Stent,2.75 mm diameter,28-29mm length,sterile**  
**Drug Eluting Coronary Stent,2.75 mm diameter,32-33mm length,sterile**  
**Drug Eluting Coronary Stent, 2.5 mm diameter,19-21mm length,sterile**

**MSD Order No: 2025/SPC/N/C/S/00221**  
**2024/SPC/A/C/S/00278**

**PA Order No: LP/DHS/SS/WW/112/01DP/2025**  
**LP/DHS/RSS/RQ/13/249DP/2024**

Re-above, details of the letter NMRA/MD/QF/23/2025 dated 27<sup>th</sup> April 2026 received from CEO/NMRA are circulated herewith for your information and necessary action, please (NMRA correspondence was received by MSD on 04.05.2026, and the SWASTHA System notification was shared on the same day)

- 1.1) Name of the product/ Item and SR : 1. **Drug Eluting Coronary Stent,2.75 mm diameter,28-29mm length,sterile**  
- **SR 13501504**  
2. **Drug Eluting Coronary Stent,2.75 mm diameter,32-33mm length,sterile**  
- **SR 13501506**  
3. **Drug Eluting Coronary Stent, 2.5 mm diameter,19-21mm length,sterile**  
- **SR 13501409**

**Sirolimus Eluting Coronary Stent System (Biomime Lineage)**

1.2) Manufacturer : Meril Life Sciences Pvt Ltd, Muktanand Marg, Chala, Vapi 396191, Gujarat, India

1.3) Batch Details :

No	Item Name and SR	Batch No	Date of Manufacture	Date of Expiry
01	Drug Eluting Coronary Stent,2.75 mm diameter, 28-29mm length, sterile  SR 13501504	BLG16	16.03.2025	15.03.2028
02	Drug Eluting Coronary Stent, 2.75 mm diameter, 32-33mm length, sterile  SR 13501506	BLG16	16.03.2025	15.03.2028

No	Item Name and SR	Batch No	Date of Manufacture	Date of Expiry
03	Drug Eluting Coronary Stent, 2.5 mm diameter, 19-21mm length, sterile  SR 13501409	BLG11	12.03.2025	11.03.2028

1.4) Reference of NMRA : To the decision of the 103<sup>rd</sup> Medical Device Evaluation Committee (MDEC)

1.5) Nature of Defects :  
- Poor trackability in reaching target lesions  
- Requirement for additional support devices due to poor trackability, leading to prolonged procedural time  
- Increased costs and higher risk of complications  
- Reports of stent dislodgements prior to deployment  
- An increased incidence of acute stent thrombosis  
- Non-uniform stent expansion which may compromise optimal vessel scaffolding and clinical outcomes

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 purview.

  
**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 23) – f.i. & n.a.   |                                     |                    |
| 22. SCO (D/WH 23)- f.i & n.a.   | 23.MSA-WH (23)/MSD - f.i. & n.a.    |                    |
| 24. MO (Technical unit)/MOH- f.i & n.a.   | 25. H/Destruction Unit (MSD) - f.i. |                    |