Circular No: **MSD/Q/S/2023/19**

My No: MSD/SCU(S)/Cir/2023
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
18-09-2023

To :
DDG/NHSL - Colombo
DDG/NH - Kandy
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 – Peritoneal Dialysis Catheter, curl cath, kit 57cm
MSD ORDER LIST NO: 2022/SPC/X/C/S/00325 **PA Order No: DHS/ICL/X/RSS/016/43PL/22**

1. Re-above, details of the letter received from CEO/NMRA (Quality log No: 3992) are given below for your information please.

1.1) Name of the product/ Item	: **Peritoneal Dialysis Catheter Kit ,Curl Cath, 57cm (Peri. Dia. Cath. Kit 57cm Curl Cath)**
SR	: **14320011**
1.2) Manufacturer	: Manish Medi Innovation, India
1.3) Batch No	: **23023196**
1.4) Date of Manufacture	: FEB.2023
1.5) Date of Expiry	: JAN.2028
1.6) NMRA Ref. No	: NMRA/MD/QF/14/2023/UR dated 06.09.2023
1.7) Nature of Defect	**: Rusty Knife, Malfunctioning discolored guide wire, introducer is not strong and has a sharp end, adapter is not connecting well to the catheter, peel off sheets was already broken.**
1.8) MDEC Recommendation	: The Medical Devices Evaluation Committee (MDEC) held on 06.09.2023 recommended to withhold the above batch from use

2. CEO-NMRA Instruction : **To withhold the above batch from use immediately**

3. Considering above facts, you are requested the following

   3.1) **To withhold the above product from use immediately.**

   3.2) To inform details of all batches available of this product to D/NMQAL, 120 Norris Canal Road, Colombo 10, to enable them to select samples for further testing and provide sample on request to NMQAL.

4. Please note: It would be your responsibility,

   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 the 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.

Dr. H.M.K. Wickramanayake,
Director,
Medical Supplies Division.

Dr. H. M. K. WICKRAMANAYAKE
Director
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw;
Colombo 10.

Cc:

1. Auditor General - f.i
2. DGHS-f.i
3. Chairman/SPC - f.i. & to inform to the supplier
4. DDG(M/S) - f.i.
5. CEO/ NMRA - f.i. & n.a.
6. Secretary/MEC - f.i
7. **D/NMQAL** - In the event that obtaining samples from 05 different batches is not possible, to inform D/MSD to send samples from available batches.
8. Chief Internal Auditor/ MOH-f.i
9. D/ (Stock Verific.)/MOH - f.i.
10. DD/MSD - f.i. & n.a.
11. Chief Accountant/MSD-f.i & n.a
12. AD(Stores)/MSD - f.i.
13. **Acct(S)MSD** - f.i.
14. AD (Dispatch)/MSD - f.i.
15. AD/ICT Unit - to publish in MSD web site
16. **AD(S I)/MSD** - To ensure that SCO concerned provide the required information to NMQAL
17. All DP/DPDHS - f.i. & n.a
18. SP / MSD - f.i & n.a
19. HSCO (S) - f.i. & n.a.
20. **SCO/(SS 12)-** To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02
21. SCO/SD(5)-f.i & n.a
22. MSA-WH (S4) MSD - f.i. & n.a.
23. MO(Technical unit)/MOH-f.i & n.a
22. H/Destruction Unit (MSD) - f.i & n.a