My No: MSD/SCU(S)/Cir/2023
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
14-07-2023

Circular No: **MSD/Q/S/2023/12**

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 Kaluthara,
All MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry

REPORT ON FAILING SAMPLE - Arterial Venous Fistula Needle 16G
MSD ORDER LIST NO: 2022/SPC/X/R/S/00298 **PA Order No: DHS/ICL/X/RS/036/110DC/22**

1. Re-above, details of the letter received from CEO/NMRA (Quality log No: 3814) are given below for your information please.

1.1) Name of the product/ Item	: **Arterial Venous Fistula Needle 16G** **Arterial & Venous Fistula Needle Rotatable Wings 16G (Starfist)**
SR	: **14301702**
1.2) Manufacturer	: St. Stone Medical Devices Private Limited ,India
1.3) Batch No	: **SF2022-01S**
1.4) Date of Manufacture	: AUG-2022
1.5) Date of Expiry	: JUL-2026
1.6) NMRA Ref. No	: NMRA/MD/QF/09/2023-BWD/RV dated 10.07.2023
1.7) Nature of Defect	: Easily rotatable needle hub which does not fixated with the shaft, Wings and the needle getting separate from the AVF, Very tight AVF needle clamp, Blunt needle and leakages, Not sharp, Short and Easily detached from adapter.
1.8) MDEC Recommendation	: **The Medical Devices Evaluation Committee (MDEC) held on 05.07.2023 recommended to revoke the batch withdrawal and discontinue to use the product with defects at the own risk of the end user. Considering that there is no alternative product is available to use and this is a lifesaving item.**
2. CEO-NMRA Instruction	: **Revoke the withdraw decision and discontinue the above batch**

3. Considering above facts, you are requested the following:

3.1) **Revoke the withdraw decision and discontinue the above batch**

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

6. Previous Circulars on same item and manufacturer:

Circular No;	Batch No:	Decision
MSD/Q/S/2023/11	SF2022-01S	Batch Withdraw

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. & n.a
4. DDG(M/S) - f.i.
5. CEO/ NMRA - f.i. & n.a.
6. Secretary/MEC - f.i
7. **D/NMQAL** – f.i
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(PII)/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 (P) - 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/PD(10)-f.i & n.a
22. MSA-WH (25)/MSD - f.i. & n.a.
23. MO(Technical unit)/MOH-f.i & n.
24. H/Destruction Unit (MSD) - f.i & n.a