

Date:- 19/02/2024

**To whom it may concern
FIELD SAFETY NOTICE (FSN)**

1. Primary Information	
Type of Field Safety Notice (FSN)	Product Recall
Type of Report	Notification
Date of Report	13/02/2024
Device Details	S-Dilator Set
Product code	BUSD0382040H
Lot No	BQ10623003
Mfg. Date	2023-Jun
Expiry Date	2026-May
Manufacture Name	BIORAD MEDISYS PVT LTD
Manufacturer Address.	Survey No. 48/3 & 48/7, Pashan-Sus Road, Sus Village, Taluka: Mulshi, Pune 41102, Maharashtra, India
Contact Person Name	Mr Babu P P
Email Address	babu@bioradmedisys.com
2. Description of the product problem	
The CE mark and EU authorised representative details were missing from the device labelling that were circulated in the Irish market.	
3. Hazard	
There is no safety risk to the patient or user. This issue is solely related to the labelling of the device.	
4. Action to be taken by the user	
Please review your stock, any devices implicated by this recall must be returned immediately to the distributor. Upon review of this notification, the user is to send acknowledgment to the distributor confirming receipt of this FSN. The distributor will return/destroy the returned affected devices as per manufacturer's instructions.	
5. Action being taken by the manufacturer	
The manufacturer will confirm the return/destruction procedure for the devices and outline this process to the distributor. Also given the training related to storage allocation separately for the CE and Non-CE labelled Products.	

G.P. Nagara I
Regulatory Department

REPLY FORM

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[Date]

We have not located any of these devices in our inventory (please add check mark to box):

I herewith acknowledge the receipt of this Field Safety Notice. Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature)

Name (Print)

Position
