



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 220 dated 23/10/2023 Regarding NCMDR
FSN of MicroINR easy control from (mfr: iLine Microsystems S.L).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 220 / 2023

نتقدم بيقين
Moving Forward
with Confidence



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23 -10-2023

Field Safety Notice of MicroINR easy control from iLine Microsystems S.L

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19722
Product	MicroINR easy control.
Description	IVD.
Manufacturer	iLine Microsystems S.L.
The affected products	EKA0005UU.
Reason	An error have been detected in the QR code on the label attached to the microINR EasyControl instructions for use. When this code is read with the microINR Expert barcode reader a message of expired lot is displayed.
Action	1. The correct QR has been attached to annex 1 in the attachment, read the QR code provided now instead of the one on the instructions for use. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





iLine Microsystems S.L
Paseo Mikeletegi, 69
Donostia-San Sebastián, Gipuzkoa
20009 SPAIN
www.ilinemicrosystems.com

MEDICAL DEVICE COMMUNICATION

(microINR EasyControl QR code incompatible with the microINR Expert Meter)

Date: 06/09/2023

Product Name	Product Code
microINR EasyControl	EKA0005UU

For the Attention of: Abdulla Fouad for Medical Supplies and Services Company.

Reason for this communication:

We have detected an error in the QR code on the label attached to the microINR EasyControl instructions for use. When this code is read with the microINR Expert barcode reader a message of expired lot is displayed.

The affected lot is: **00230418**.

Please Take the Following Actions:

We attach to this communication an annex with the correct QR code for the affected microINR EasyControl lot you have received during 2023. If any client is using this lot with the microINR Expert Meter, they should read the QR code provided now instead of the one on the instructions for use. The microINR Expert Meter has also the option of using the microINR EasyControl as an external quality control material and in this case a QR code is not required.

Please, share with any final user using the microINR EasyControl with microINR Expert meters the new QR code we provide in this communication.



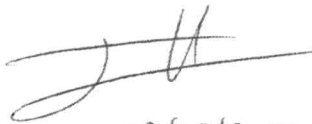
iLine Microsystems S.L
Paseo Mikeletegi, 69
Donostia-San Sebastián, Gipuzkoa
20009 SPAIN
www.ilinemicrosystems.com

Actions Taken by iLine Microsystems:

We have opened a Corrective and Preventive Action (CAPA) to update the internal instruction of generating the QR code compatible with the microINR Expert Meter.

Contact information:

Itsaso Hormaeche, PhD




06/09/2023



RAQS Director (*date and signature*)

Annex 1- microINR EasyControl. Correct QR label

microINR EasyControl Lot	Message on the microINR Expert	Correct label
00230418	Expired	



iLine Microsystems S.L
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www.ilinemicrosystems.com

Customer Response Form

(Indicate the communication reason)

Please assist iLine Microsystems by promptly returning this form to:

(email) quality@ilinemicrosystems.com

CUSTOMER INFORMATION :

Facility: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Contact Person: _____

Telephone No.: _____ email Address: _____

I have read and understood the medical device communication.

I agree to carry out the actions required in the medical device communication.

Name:	
Title:	
Signature/Date:	