



URGENT: MEDICAL DEVICE PRODUCT CORRECTION
2nd NOTICE - IMMEDIATE ACTION REQUIRED

February 10, 2023

GM MEDICAL A/S
BLOKKEN 11
BIRKEROD, 3460
DENMARK

Dear SunMed Customer,

This letter is to inform you of a product notification involving Air-Q3 G and Air-Q3 SPG ILA models with gastric access manufactured by Cookgas LLC.

It has been brought to our attention that the labeling in the instructions for use (IFU) and the printed text on the device indicate an orogastric (OG) tube size discrepancy. The correct recommended maximum OG Tube/Catheter sizes for each Air-Q3G and Air-Q SPG model are included in the table below for user reference.

Code (Manual Inflation and SP)	Air-Q3 Size	Correct OG Tube Size (Fr)
50005, 60005	0	5
50055, 60055	0.5	6
50105, 60105	1	8
50155, 60155	1.5	8
50205, 60205	2	10
50305, 60305	3	14
50405, 60405	4	16
50505, 60505	5	18

The product has been evaluated as safe to use. If you have further distributed this product, please identify your customers and notify them of the correct maximum gastric tubes. Your notification to your customers may be enhanced by including a copy of this notification letter and encouraging them to post the table as a reminder.

Please instruct your end-users to complete the attached response form and return it to you even if there is no affected product on hand. Additionally, the UDI list is attached. SunMed is committed to quality and appreciates your business.

Colleen Glynn
Vice President, Marketing

Enclosure: Product Notification Response Form and UDI list

Toll Free 800-433-2797
T 616-259-8400
F 616-647-3430

www.Sun-Med.com
2710 Northridge Dr. NW, Suite A
Grand Rapids, MI 49544



Immediate Action Requested

Product Notification Response Form

Please check ALL appropriate boxes.

- I have read and understand the letter instructions provided in the letter sent January 9, 2023.
- I have further distributed the affected device and will notify the receiving facility by (**specify date & method of notification**): _____.
- If applicable, I have notified appropriate regulatory authorities of this Medical Device Correction (**specify date & method of notification**): _____.

Have any adverse events been reported to you regarding the affected product? Yes No

If yes, please explain: _____

Please complete the following section:

Contact Name: _____

Title: _____

Facility Name: _____

Address: _____

City/State/Zip Code: _____

Telephone Number: _____ Email: _____

PLEASE SEND COMPLETED RESPONSE FORM TO:

FAX # **1-800-400-8820** ATTN: Product Quality or E-MAIL TO: productquality@sun-med.com



UDI numbers associated with each impacted SKU:

REF Number	Product Description	UDI
50005	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 0.0	Each: 00814954020188 Box: 10814954020185 Case: 20814954020182
50055	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 0.5	Each: 00814954020195 Box: 10814954020192 Case: 20814954020199
50105	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 1.0	Each: 00814954020201 Box: 10814954021007 Case: 20814954020205
50155	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 1.5	Each: 00814954020218 Box: 10814954021014 Case: 20814954020212
50205	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 2.0	Each: 00814954020225 Box: 10814954021021 Case: 20814954020229
50305	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 3.0	Each: 00814954020232 Box: 10814954021038 Case: 20814954020236
50405	AirQ3 Standard ILA with Manual Cuff Inflation and GA Size 4.0	Each: 00814954020249 Box: 10814954021045 Case: 20814954020243
60005	AirQ3 Self Pressurizing ILA with Automatic Cuff Inflation and GA Size 0.0	Each: 00814954020263 Box: 10814954020260 Case: 20814954020267
60055	AirQ3 Self Pressurizing ILA with Automatic Cuff Inflation and GA Size 0.5	Each: 00814954020270 Box: 10814954020277 Case: 20814954020274
60105	AirQ3 SP ILA with Auto Cuff Inflation and GA Size 1.0	Each: 00814954020287 Box: 10814954021083 Case: 20814954020281
60155	AirQ3 SP ILA with Auto Cuff Inflation and GA Size 1.5	Each: 00814954020294 Box: 10814954021090 Case: 20814954020298
60205	AirQ3 SP ILA with Auto Cuff Inflation and GA Size 2.0	Each: 00814954020300 Box: 10814954021106 Case: 20814954020304
60305	AirQ3 SP ILA with Auto Cuff Inflation and GA Size 3.0	Each: 00814954020317 Box: 10814954021113 Case: 20814954020311
60405	AirQ3 SP ILA with Auto Cuff Inflation and GA Size 4.0	Each: 00814954020324 Box: 10814954021120 Case: 20814954020328

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