Class 2 Device Recall GEM Premier 5000

See Related Information[22]

Date Initiated by Firm	May 08, 2026
Date Posted	July 29, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-2826-2026
Recall Event ID	99115[23]
510(K)Number	K203790[24]
Product Classification	Electrode measurement, blood-gases (pco2, po2) and blood ph[25] - **Product Code** CHL[26]
Product	Brand Name: GEM Premier 5000 Product Name: GEM Premier 5000 Model/Catalog Number: 00024019255 Portable blood analyzer system
Code Information	GEM Premier 5000: Part number: 00024019255 UDI: 08426950870227 Units distributed in Argentina: GEM Premier 5000 Serial Nos.: 25100466, 24097933 and 23064897. Affected Accessory: Bar Code Reader (BCR) Wand that received a configuration update on or after 8 April 2026. Part No. 00024015859; UDI No. 08426950869634
FEI Number	1217183
Recalling Firm/ Manufacturer	Instrumentation Laboratory 180 Hartwell Rd Bedford MA 01730-2443
For Additional Information Contact	781-861-4467
Manufacturer Reason for Recall	Potential for Bar Code Reader (BCR) wands, used with the GEM Premier 5000 and GEM Premier 7000 systems, to assign patient results to an incorrect patient ID.
FDA Determined Cause [2]	Software Design Change
Action	Werfen dba Instrumentation laboratory notified consignees on about 05/08/2026 via letter and/or email. Consignees were instructed to discontinue use of the affected BCR wands immediately, manually enter patient IDs when performing testing on the GEM Premier 5000 and/or 7000 until the BCR wands have been replaced, contact Werfen Service at 1-800-955-9525 to arrange for prompt replacement of the affected BCR wands, post this notification on or near affected GEM Premier 5000 and/or 7000 instruments, and inform all laboratory staff of this notification. Consignees were also instructed to forward the notification to all affected locations within each facility, retain a copy of the notification for records, and complete and return the Mandatory Response Tracking Form within 10 days of receipt. In addition to the tracked customer notification, a Service Information (SI) 2026-09

	was issued on May 11, 2026, for service personnel to track the destruction of the affected BCR wands. The Service Information includes a destruction form for service personnel to document the destruction of the affected BCR wands and to return the form to Regulatory for tracking purposes.
Quantity in Commerce	3
Distribution	US Nationwide distribution.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = CHL[29]

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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
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