DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	12/15/2025-12/18/2025 FEI NUMBER 3003749380

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gilbert J Ameryckx , President and CEO

FIRM NAME	STREET ADDRESS
DiAgam Societe Anonyme (S.A.)	Rue Du Parc Industriel 40
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ath, Hainaut, 7822 Belgium	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, your firm's process validation procedures: *Validation et modification des processus et des équipments* DGM-QAA-SOP-023 Rev 00 (dated JAN-25-2019) to Rev 03 (dated JULY-23-2024) and *Quality Management,* SOP-IMP-04 Ver 1 (dated MAY-26-2025) are inadequate. Between [(b)(4)] [(b)(4)] your firm has distributed approximately [(b)(4)] (A2M-1) and [--] (A2M-2) Alpha2-Macroglobulin immunoturbidimetry IVD kits (Class II), [--] IVD calibrator Kits (Class II), and [--] IVD control kits (Class I). Your firm failed to adequately validate the process of:

A. Capping the IVD, Control, and Calibrator vials specific to Bouchoneuse 1 'Capper 1'. Specifically, your firm's validation *Qualification et Validation de la Visseuse à bouchon semi-automatique,* DGM-R+D-NOT-14011b (dated FEB-25-2014) fails to provide any assurance that the:
   1. Machine TB440.4 is capable of producing product that meets specifications. Specifically, your firm failed to include any protocol, testing instructions, acceptance criteria, and results for the installation/qualification of the capping machine.
   2. Process was challenged utilizing worst case process parameters which include but are not

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limited to capping head type, capping head life, torque, height, and vial size.

3. Process can reliably operate in a state of control and consistently produce conforming product under nominal operating conditions and process settings at production quantities.

Between [redacted] (b)(4), your firm has processed approximately [redacted] (A2M-1) and [redacted] (A2M-2)Alpha2-Macroglobulin immunoturbidimetry IVDs vials (Class II), [redacted] IVD calibrator vials (Class II), and [redacted] IVD control vials (Class I) using Bouchoneuse 1 'Capper 1'

B. Capping the IVD, Control, and Calibrator vials specific to Bouchoneuse 2 'Capper 2'. Specifically, your firm's *Validation de la seconde bouchoneuse,* DGM-R+D-NOT-20026 (dated SEPT-23-2020) fails to provide any assurance that the

1. Machine TB440.4 is capable of producing product that meets specifications. Specifically, your firm failed to include any protocol, testing instructions, acceptance criteria, and results for the installation/qualification of the capping machine.
2. Process was challenged utilizing worst case process parameters which include but are not limited to capping head type, capping head life, torque, height, and vial size.
3. Process is capable of producing conforming product across all capping head types and vial sizes. For example, in *Qualification de 3 nouvelles têtes de bouchonneuse* DGM-R+D-NOT-24018 (dated JUNE-20-2024) your firm did not include any testing in the operational qualification and only included a quantity of [redacted] vials used in the PQ for capper head #10.
4. Process can reliably operate in a state of control and consistently produce conforming product under nominal operating conditions and process settings at production quantities.

Between [redacted] (b)(4) your firm has processed approximately [redacted] (A2M-1) Alpha2-Macroglobulin immunoturbidimetry IVDs vials (Class II), [redacted] IVD calibrator vials (Class II), and [redacted] IVD control vials (Class I) using Bouchoneuse 2 'Capper 2'

C. Testing the IVD kits using the [redacted] (b)(4) analyzer. Specifically, your firm has no assurance

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that the analyzer can consistently detect nonconforming volumetric failures associated Alpha2-Macroglobulin immunoturbidimetry IVD kits (Class II).

OBSERVATION 2

The appropriate design, construction, placement, and installation of manufacturing equipment have not been ensured and equipment used in the manufacturing process does not meet specified requirements.

Specifically, your procedures which govern capping *Short-term maintenance Bouchonneuse,* FOR-INF-02_BOUCHONEUSE Rev 01 (dated JULY-01-2025) and Maintenance et métrologie Rev 35 (dated JULY-30-2024) and Rev 34 (dated OCT-27-2022) are inadequate. For example:

A. Your firm consistently operates outside the validated parameters for capping height processed. Of the 5 DHRs reviewed the following was observed:

Head No.	Capper No.	Validation	Height in Validation	Observed Height Range
2	1	DGM-R+D-NOT-14011B		
2	1	DGM-R+D-NOT-14011B		
3	1	DGM-R+D-NOT-14011B		
3	1	DGM-R+D-NOT-14011B		
3	1	DGM-R+D-NOT-14011B		
3	1	DGM-R+D-NOT-14011B		
2	1	DGM-R+D-NOT-14011B		
2	1	DGM-R+D-NOT-14011B		

(b)(4)

B. Your firm has not defined the end-of-life characteristics and maintenance requirements of your custom capping heads #2, #3, #6, #7, #10, #11 used in the manufacturing of the Alpha2-

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Naakesh N Gomanie
Investigator
Signed By: NAAKESH N. GOMANIE -S
Date Signed: 12-18-2025 16:01:27

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Macroglobulin immunoturbidimetry IVD kits (Class II), IVD calibrator Kits (Class II), and IVD control kits (Class I).

OBSERVATION 3

Procedures for finished device acceptance have not been adequately established.

Specifically, your firm's *Procedure de controle final des commades *** diagnostics GMBH*, DGM-QAC-SOP-030 Rev 08 (dated JAN-31-2023) fails to require any testing of the capping process for the Alpha2-Macroglobulin immunoturbidimetry IVD kits (Class II), IVD calibrator Kits (Class II), and IVD control kits (Class I).

OBSERVATION 4

Procedures for the acceptance and control of in-process product have not been established.

Specifically, your firm has not established any in-process inspection procedures for the Alpha2-Macroglobulin immunoturbidimetry IVD kits (Class II), IVD calibrator Kits (Class II), and IVD control kits (Class I).

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."