

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000451870-PA-NA-BRA

Initial certification date:
25 June 2021

Valid:
25 June 2024 – 24 June 2027

This is to certify that the management system of
WERFEN MEDICAL LTDA
Av. Tamboré, 267, Ed. Canopus, 06.460-000, Barueri, SP, Brazil
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

**IMPORT, STORAGE, SALE, DISTRIBUTION, INSTALLATION AND TECHNICAL ASSISTANCE SERVICE FOR IN VITRO DIAGNOSTIC EQUIPMENT.
IMPORT, STORAGE, SALE, DISTRIBUTION AND ASSISTANCE SERVICE FOR IN VITRO DIAGNOSTIC PRODUCTS INCLUDING REAGENTS AND CONSUMABLES.**

Place and date:
Høvik, 17 April 2024



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative



DNV

Certificate no.: 10000451870-PA-NA-BRA
Place and date: Høvik, 17 April 2024

Appendix to Certificate

WERFEN MEDICAL LTDA

Locations included in the certification are as follows:

| Site Name | Site Address | Site Scope |
|---------------------|---|---|
| WERFEN MEDICAL LTDA | Av. Tamboré, 267, Ed. Canopus, 06.460-000, Barueri, SP, Brazil | SALE, INSTALLATION, TECHNICAL ASSISTANCE SERVICE FOR IN VITRO DIAGNOSTIC PRODUCTS INCLUDING EQUIPMENT, REAGENTS AND CONSUMABLES. |
| WERFEN MEDICAL LTDA | Rodovia Antonio Heil, nº 4605, Módulo K Frente – Itaipava, 88.316-003, Itajaí, SC, Brazil | IMPORT, STORAGE, DISTRIBUTION, TECHNICAL ASSISTANCE SERVICE FOR IN VITRO DIAGNOSTIC PRODUCTS INCLUDING EQUIPMENT, REAGENTS AND CONSUMABLES. |

