

Management System Certificate

Certificate No.: 10000451870-PA-NA-BRA Rev 0.0

Initial Certification Date: 25 June 2021

Valid Until 24 June 2024

This is to certify that the quality system of:

Werfen Medical Ltda

Avenida Tamboré, 267, Edifício Canopus - Torre Sul - 25º andar – Alphaville – Barueri, São Paulo, 06460-000, 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/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

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

Place and date:
Høvik, 25 June 2021

Check Validity



For the issuing office:
DNV Product Assurance AS

Tone Elise Kolpus
Lead Auditor

icate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Site Name	Address	Site Scope
Werfen Medical Ltda – SITE 1	Avenida Tamboré, 267, Edifício Canopus - Torre Sul - 25º andar – Alphaville – Barueri, São Paulo, 06460-000, Brazil	SALE, INSTALLATION, TECHNICAL ASSISTANCE SERVICE FOR IN VITRO DIAGNOSTIC PRODUCTS INCLUDING EQUIPMENT, REAGENTS AND CONSUMABLES.
Werfen Medical Ltda – SITE 2	Rodovia Antonio Heil, 4605, Itaipava – Itajaí, Santa Catarina, 88316-003, Brazil	IMPORT, STORAGE, DISTRIBUTION, TECHNICAL ASSISTANCE SERVICE FOR IN VITRO DIAGNOSTIC PRODUCTS INCLUDING EQUIPMENT, REAGENTS AND CONSUMABLES.

