



Quality Management System Certificate EN-ISO 13485:2016

The certificate:

23M00077CRT01

issued by:

to: Manufacturer Address Kiwa Dare B.V. Vijzelmolenlaan 7 3447 GX Woerden The Netherlands

MediTop B.V. Vlasakker 22 3417 XT Montfoort The Netherlands

Tradenames:

Entermed

Regarding the scope:

- Design, development, manufacturing, installation, distribution and service of treatment systems for the

area of ENT (ear, nose and throat).

- Design, development, manufacturing and service of wound drainage pumps for the area of acute,

institutional and long-term care and in home care.

- Distribution of medical products for the area of ENT.

This certificate is based on the following documents: 23M00007PRP01

Kiwa Dare B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 + A11:2021 and that all requirements of the standard and its implementation are fulfilled.

The validity of this certificate is three years and includes the surveillance obligations of EN-ISO 17021-1:2015.

Issued for the first time: Reissued: Re-certification: Valid to: 04 June 2020 NA 04 June 2023 04 June 2026

Kiwa Dare B.V.

Dr. N. Cuper Certification decision maker

Ing. D. Van der Vlugt Director

