EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Hospitech Respiration Ltd. 15 Atir Yeda Street Kfar Saba, 446312 Israel

for the scope

AnapnoGuard 100s Respiratory Guard System (for controlling EndoTracheal Tube Cuff Pressure and Evacuation of Subglottic Secretions) consisting of:
AnapnoGuard 100s Control Unit (AG100s) and
AnapnoGuard Connection Kit (AG Connection Kit - Harness)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

 Valid from
 2018-08-16

 Valid until
 2023-08-15

 Registration no.
 D1208200011

 Report no.
 P18-00667-126959

 Striffpart
 2010-08-45

Stuttgart 2018-08-15

Head of Certification Body





Internet: http://www.mdc-ce.de