EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Rapid Medical Ltd.

Carmel Building
POB 337
Yokneam Elite 2069205
Israel

that the design of the following device(s)

Tigertriever Revascularization Device in the variants according to annex

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 505745 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:

ANTR-0126-Tigertriever Technical File-rev.10 dated 2019-07-02
Tigertriever Submission 091219 dated 2019-12-09
Tigertriever XL submission dated 2020-03-03
Tigertriever Plus submission dated 2020-12-18

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report:

411_18e_Report_TFR_Tigertriever_R2019_V1 dated 2019-08-28
411_18e_Report_TFR_Sample_TT_V5 dated 2019-12-19
411_18e_Report_TFR_Tigertriever_R2019_V1 dated 2020-05-23
0_411_18e_Report_TFR_Tigertriever_R2019_V4.docx dated 2021-02-11

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	524815 MRA
Certificate unique ID	170774378
Effective date	2021-02-11
Expiry date	2024-05-26
Frankfurt am Main	2021-02-11

Digitally signed by Ostapciuc Alexandr
Date: 2021.11.19 16:56:42 EET
Reason: MoldSign Signature
Location: Moldova

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.23 Version 1.0

Annex to certificate
Certificate registration No.: 524815 MRA
Certificate unique ID: 170774378
Effective date: 2021-02-11

Rapid Medical Ltd.

Carmel Building
POB 337
Yokneam Elite 2069205
Israel

Model Number	Product name
TRPP3155	Tigertriever
TRPP3166	Tigertriever 17
TRPP3144	Tigertriever 13
TRPP3133	Tigertriever XL
TRPP3122	Tigertriever Plus