



ALLEVA MEDICAL LTD.

康智科學有限公司

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EC Declaration of Conformity

Manufacturer:

Alleva Medical Limited

Suite M-Q, 12th Floor, Kings Wing Plaza 2

1 On Kwan Street, Shek Mun, Shatin

N.T., Hong Kong

Tel: +852 3166 7200

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We, the manufacturer, herewith declare that the following product:

extriCARE® Negative Pressure Wound Therapy System

The products concerned has been designed and manufactured under a quality management system and in conformity to the following standards or other normative documents:

ISO 10079-3 Third Edition 2014-05-01 Medical suction equipment-Part 3: Suction equipment powered from a vacuum or positive pressure gas source, and CFR 878.4780. The devices were listed on FDA under 510K, K110078, K131464, K132252, K140634, K143362 and K132225.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

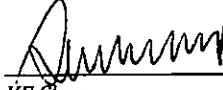
The above mentioned declaration of conformity is exclusively under the responsibility of

Alleva Medical Limited

Suite M-Q, 12th Floor, Kings Wing Plaza 2, 1 On Kwan Street

Shek Mun, Shatin, N.T., Hong Kong

August 17, 2020


KF Chan
Director, QA & RA

