

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: Guangdong Yuehua Medical Instrument Factory Co., Ltd.
/
Rongsheng Science and Technology Zone, Daxue Road, 515063
Shantou, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000004539

EU Authorized Representative:/ Eunitor GmbH
ADD: Kennedydamm, 5, Düsseldorf, 40476, Germany.
SRN: DE-AR-000005081

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device:

Name of the medical device: / Alternating Pressure Mattress

Basic UDI-DI: / 694474954001M4, 694474954005MC,
694474950030LF, 694474954004MA, 694474954006ME,
694474950047LY, 694474950082M2, 694474950053LT,
694474950055LX

Product model:/ QDC-303, P4000IIE(B), QDC-303+P4000IIE(B),
QDC-300B, P4000IIE(C), QDC-300B+P4000IIE(C),
QDC-5010E+P3000N2EB, QDC-8010+P3000A2QB3,
QDC-8080+P3000A2QB3

Product code:/ EMDN CODE: V080701, ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES

Intended purpose: / Prevent pressure sore in bedridden patients.

Trade name:/



of class: / Rule 1, Class I

is in conformity with Regulation (EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure:/ Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 /



CS reference: / None

2022.11.16
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Leonlin
Name und Funktion / Name and function /
Nom et fonction / Nome e funzion