

Manufacturer's Declaration of Conformity

PRODUCT IDENTIFICATION.

Pressure relief Mattress systems (Type 19)

(Dynamic mattresses and cushion systems for pressure ulcer prevention and therapy)

QUATTRO ACUTE Range

QUATTRO PLUS Range

QUATTRO OVERLAY Range

PULSAIR CHOICE Range

B.A.S.E. Range

FUSION Hybrid

Sentinel

DECLARATION

The above Class 2a classification rule 9 Medical Device's conforms with Directive (93/42/EEC) Annex II (excluding Section 4) as amended 2007/47/EC and the European RoHS Directive (2011/65/EU). All supporting documentation is retained at the premises of the manufacturer.

Standards: IEC 60601-1 Electrical safety.
IEC 60601-1-11 Home health care.
BS/EN 60601.1.2 EMC.
Class II, Type BF, IP21.
120V 60Hz. 230V 50Hz. 240V 60Hz.

UNSPSC Code: 42000000 - Medical Equipment and Accessories and Supplies.

GMDN Code: 63241 - Alternating Mattress systems.

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Notified Body Number: 1639

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Representative:**

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Signed:

R. W. Macdonald.

Date:

14/10/2020

Regulatory Affairs Manager.



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