**Talley Group Limited**
Premier Way, Abbey Park Industrial Estate
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# 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
AUTOCURA Range
QUATTRO OVERLAY Range
PULSAIR CHOICE Range
B.A.S.E. Range
SENTINEL Range
LC600 Range
QUATTRO FUSION

**DECLARATION**

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

| | |
|---|---|
| Standards: | IEC 60601-1 (3rd edition) BS/EN 60601-1:2006 Electrical safety.<br>IEC 60601-1-11 Home health care.<br>Intertek ltd report no. 101068182LHD-004.<br><br>BS/EN 60601.1.2 EMC.<br>Hursley EMC Services report no. 10R451 MR.<br><br>Class II, Type BF, IP21.<br>120V 60Hz. 230V 50Hz. 240V 60Hz. |
| UNSPSC Code: | 42000000 - Medical Equipment and Accessories and Supplies. |
| GMDN Code: | 47478 - Alternating Mattress systems. |
| Manufacturer: | Talley Group Limited, Premier Way, Abbey Park Industrial Estate, Romsey, Hampshire SO51 9DQ England. |
| Notified Body: | SGS United Kingdom Limited, Unit 202B, Worle Parkway, Somerset BS22 6WA England. Notified Body Number 0120 |

Signed: R. W. Macdonald. Date: 15/06/2016

Quality and Regulatory Affairs Manager.

GREAT BRITISH DESIGN AND MANUFACTURING SINCE 1953



Directors C P Evans, I J H Evans, M B Webb, K P Means
Registered in England No. 520386
Registered Office Tomngton House, 8 Holywell Hill, St Albans, Herts AL1 1HD

EC Certificate Full Quality Assurance System: Certificate GB19/964121

The management system of

# Talley Group Ltd

Manufacturing Site: Premier Way (Unit 1), Abbey Park Industrial Estate,
Romsey, Hampshire, SO51 9DQ, UK

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4)**

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 30 October 2019 until 05 November 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 11 May 1998
and first certified by SGS Belgium on 30 October 2019

Certification is based on reports numbered GB/PC 08878

Authorised by

Pieter Weterings
Certification Manager


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# Talley Group Ltd

# Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4).**

Issue 1

Detailed scope

**Pneumatic compression therapy equipment for the treatment of Deep Vein Thrombosis, Lymphedema, venous insufficiency and chronic non-healing wounds and ulcers:**
**Type 19 Compression SYNCHRO**
**Pneumatic compression therapy pump [DVT].**
**VENTURI™ negative pressure wound therapy system.**
**Compact VENTURI™ negative pressure wound therapy system.**
**VENTURI™ MiNO negative pressure wound therapy system.**

**Sterile Negative Wound Therapy Dressing Packs:**

**Sterile Foam Pads**
**Type 19 Active support surfaces [Dynamic mattress and cushion systems for pressure ulcer prevention and therapy]**
**TG600/07 Active support surfaces [Dynamic mattress and cushion systems for pressure ulcer prevention and therapy].**

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