

## Technical File



## EC Declaration of Conformity

We: Orvec International Ltd

Of:  
Malmo Road  
Sutton Fields  
Hull  
HU7 0YF  
United Kingdom

Declare that Class 1 Medical incorporating ORVEWRAP+

### Product Codes:

- CAR+WR10N+03 Saana Poncho
- CAR+WR10N+04 Salla Poncho
- CAR+WR10N+02 Levi blanket
- CAR+HB30n+02,04 Pallas Hypothermia bag

Patient specific products:

- Linen packs CAR+AP10N+\*\* (01, 02, 03, 04)

In accordance with the following Directive: **93/42/EEC**

Conforms with the essential requirements of the Medical Directive as amended by 2007/47/EC and is in conformity with the procedures set out in Annex VII of Council Directive 93/42/EEC

Signed By

Kevin Stamp  
Managing Director

Dated: 11/10/2017