



Konformitätserklärung Declaration of Conformity

Produktspezifikation / product details:

Produktbezeichnung / product name	RedVac Vacuum Mattress
Type / type	VM820E
Klassifizierung nach RL 93/42/EWG, Anhang IX / Classification according 93/42/EEC, Annex IX	Klasse I nach Regel 1 / Class I per rule 1

Konformitätsbewertung / assessment details:

Verfahren nach RL 93/42/EWG / Route of directive 93/42/EEC	Anhang VII (EG-Konformitätserklärung) / Annex VII (EC Declaration Of Conformity)
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Bewertungs details:

notified body	SIQ Ljubljana Notified Body ID no. 1304
Route of directive 93/42/EEC	Annex VII
Certificates	SIQ SI-M-137

Angewandte Normen / used standards:

Harmonisierte Normen / harmonized standards	EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008
Sonstige Normen / other standards:	EN 1865-1:2010 + A1:2015, EN 1865-2:2010 + A1:2015, EN 1789:2007 + A2:2014

We declare under sole responsibility that the products described above are in compliance with the applicable requirements of the directive 93/42/EEC as latest amended and of the Austrian medical-device-law BGBl. 657/1996 as latest amended. The products are CE marked.



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