



DECLARATION of CONFORMITY (DoC)

We (manufacturer): Qualiteam s.r.l.
Loc. Nassio Sopra, 15/A
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declare under our sole responsibility for the product:

Name: QualiBelly Advanced postoperative abdominal binder

Model codes:	Toddler:	QLY TOD	(UDI-DI 8033675190624)
		QLY2 TOD	(UDI-DI 8033675190631)
	Pediatric:	QLY PED	(UDI-DI 8033675190617)
		QLY2 PED	(UDI-DI 8033675190648)
	Adult:	QLY - S	(UDI-DI 8033675190204)
		QLY - M	(UDI-DI 8033675190303)
		QLY - L	(UDI-DI 8033675190402)
		QLY - XL	(UDI-DI 8033675190501)
		QLY - XXL	(UDI-DI 8033675190600)
		QLY - XXXL	(UDI-DI 8033675192994)
		QLY - 4XL	(UDI-DI 8033675190426)
		QLY40 - S	(UDI-DI 8033675192208)
		QLY40 - M	(UDI-DI 8033675192215)
		QLY40 - L	(UDI-DI 8033675192222)
		QLY40 - XL	(UDI-DI 8033675192321)
		QLY40 - XXL	(UDI-DI 8033675192420)
	QLY40 - XXXL	(UDI-DI 8033675192512)	
	QLY40 - 4XL	(UDI-DI 8033675190389)	

Object:

The QualiBelly Advanced abdominal binder is a compression device that supports the patients upper-, mid- and lower abdomen postoperatively after major surgeries such as interventions in the abdominal organs and vascular system, abdominoplasty, weight loss surgery and hernia surgeries. QualiBelly Advanced protects the wound and helps patients to manage pain during activity, coughing, sneezing and straining. It improves posture, promotes free movement and early recovery.



That the product is in conformity with the Medical Device Directive Regulation 2017/745/EU (MDR) which classifies this non-sterile product as a low risk Class I device.

The QualiBelly Advanced Technical Dossier is available at the address listed above.

Chiaverano, December 1, 2019

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