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## EC DECLARATION OF CONFORMITY Certificate No: 019

**Manufacturer:** L&R Medical UK Ltd, 1 Wellington Court, Lancaster Park, Needwood, Burton upon Trent, Staffordshire, DE139PS

**General Product Name:** ActiFast Two Way Stretch Tubular Retention Bandage (see appendix 019 for product details)

**Intended Use:** For use in dressing retention. For use with the wet wrap technique

**Single Registration Number:** Not Applicable

**Authorised Representative:** Lohmann & Rauscher International GmbH & Co. KG, Westerwaldstrasse 4, DE-56579 Rengsdorf, Germany

**Conforming to Product Standards:** Drug Tariff specification 46 for lightweight elasticated viscose tubular bandage

**Standards Applied :** BS EN ISO9001:2015 BS EN ISO13485:2016 BS EN ISO14971:2019

**GMDN Code:** 35374

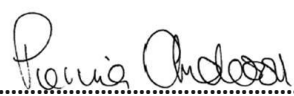
**Basic UDI-DI:** Not applicable

**Notified Body:** Not applicable

**Directive Classification No:** Class I, D1

**Conformity assessment route:** L&R Medical UK Ltd uses procedures for the CE-labelling of their products according to the Regulation MDR 2017/745

This declaration of conformity is issued under the sole responsibility of L&R UK Ltd. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality Management System approval to ISO 13485:2016. All supporting documentation is retained at the premises of the manufacturer.

**Signed:**  .....

**Dated:** 01 May 2021

**Name:** Pierina Anderson

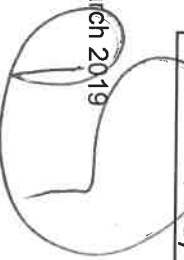
**Position:** Quality & Regulatory Manager



Lohmann & Rauscher

Product Description	Colour	Size	Pip Code	EAN Product Codes	L&R UK (SAP) Code
ActiFast Two Way Stretch Tubular Retention Bandage	Red	3.5cm x 1m	285-6490	5037696400352	88573
ActiFast Two Way Stretch Tubular Retention Bandage	Red	3.5cm x 10m	285-6508	5037696400314	88574
ActiFast Two Way Stretch Tubular Retention Bandage	Green	5cm x 1m	285-6516	5037696400277	88575
ActiFast Two Way Stretch Tubular Retention Bandage	Green	5cm x 3m	285-6524	5037696400260	88576
ActiFast Two Way Stretch Tubular Retention Bandage	Green	5cm x 5m	285-6532	5037696400253	88577
ActiFast Two Way Stretch Tubular Retention Bandage	Green	5cm x 10m	285-6540	5037696400338	88578
ActiFast Two Way Stretch Tubular Retention Bandage	Blue	7.5cm x 1m	285-6557	5037696400246	88579
ActiFast Two Way Stretch Tubular Retention Bandage	Blue	7.5cm x 3m	285-6565	5037696400239	88580
ActiFast Two Way Stretch Tubular Retention Bandage	Blue	7.5cm x 5m	285-6573	5037696400222	88581
ActiFast Two Way Stretch Tubular Retention Bandage	Blue	7.5cm x 10m	285-6581	5037696400345	88582
ActiFast Two Way Stretch Tubular Retention Bandage	Yellow	10.75cm x 1m	285-6599	5037696400307	88583
ActiFast Two Way Stretch Tubular Retention Bandage	Yellow	10.75cm x 3m	285-6615	5037696400291	88584
ActiFast Two Way Stretch Tubular Retention Bandage	Yellow	10.75cm x 5m	285-6623	5037696400284	88585
ActiFast Two Way Stretch Tubular Retention Bandage	Yellow	10.75cm x 10m	285-6631	5037696400321	88586
ActiFast Two Way Stretch Tubular Retention Bandage	Beige	17.5cm x 1m	292-4298	5037696400543	88587
ActiFast Two Way Stretch Tubular Retention Bandage	Beige	17.5cm x 10m	290-5750	5037696400611	88588
ActiFast Two Way Stretch Tubular Retention Bandage	Purple	20cm x 1m	369-0302	5037696100979	31980
ActiFast Two Way Stretch Tubular Retention Bandage	Purple	20cm x 5m	369-0310	5037696100986	31982
ActiFast Two Way Stretch Tubular Retention Bandage	Purple	20cm x 10m	369-0328	5037696100993	31981

Date: 12 March 2019  
Issue: 4.2



Approved: P Anderson