

EC Declaration of Conformity

We hereby declare that the medical device(s) specified below meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, and they are classified as a Class I (sterile) medical device under rule no.4.

This declaration of conformity is issued under the sole responsibility of Reliance Medical (Shanghai) Ltd. (EUDAMED SRN CN-MF-000007382), the Manufacturer, located at Building 94, Lane 328, Hengyong Road, Jiading District, Shanghai, China.

We have appointed Reliance Medical (Ireland) (EUDAMED SRN IE-AR-000003675), located at Unit 17, Westlink Industrial Estate, Kilemore Road, Dublin 10, Ireland, as our EU Authorized Representative for these products.

Compliance of the specified devices with the Regulation has been assessed and certified by our Notified Body, TÜV Rheinland LGA Products GmbH (0197), who has issued certificate DZ 1561505-1 using the conformity assessment described in Annex XI Part A of the Regulation. The certificate is limited to aspects relating to establishing, securing and maintaining sterile conditions.

This declaration applies to all batches released under the control of the technical file RSMH CE-05-00, version 3A.

Signed:

Person Responsible for Regulatory Compliance
On behalf of Reliance Medical (Shanghai) Ltd

Jay. Jim

Date:

2024.06.13

Place:

Shanghai, China



Product REF	Basic UDI-DI	EMDN	UDI-DI	Product Description
2204	506013188CE05BRG	M040101	05060186998763	Dependaplast Fabric Plasters Traditional Heavyweight 7.5cm x 2.5cm Box of 100
2205	506013188CE05BRG	M040101	05060186998787	Dependaplast Fabric Plasters Traditional Heavyweight 7.5cm x 5cm Box of 50
2210	506013188CE05BRG	M040101	05060186998800	Dependaplast Fabric Plasters Traditional Heavyweight Assorted Box of 100
2211	506013188CE05BRG	M040101	05060186998831	Dependaplast Fabric Plasters Traditional Heavyweight Assorted Plastic Box of 120
2212	506013188CE05BRG	M040101	05060186998848	Dependaplast Fabric Plasters Traditional Heavyweight 2cm x 12cm (Finger Extension) Box of 50
2215	506013188CE05BRG	M040101	05060738577798	Protect Tough Fabric Plasters Traditional Heavyweight Assorted Box of 20
2224	506013188CE05BRG	M040101	05060497990098	Dependaplast Fabric Plasters Traditional Heavyweight 7.5cm x 2.5cm
2225	506013188CE05BRG	M040101	05060497990101	Dependaplast Fabric Plasters Traditional Heavyweight 7.5cm x 5cm
2226	506013188CE05BRG	M040101	05060497990111	Dependaplast Fabric Plasters Traditional Heavyweight Fingertip
246	506013188CE05CRJ	M040101	05060131882468	Dependaplast Fabric Plasters Assorted Box of 120
2520	506013188CE05CRJ	M040101	05060738577736	Protect Lite Fabric Plasters Assorted Box of 20
32774	506013188CE05ARE	M040101	05060147330076	Medikit Elite Pack of 10 wasproof plaster - CASE OF 1200
32776	506013188CE05ARE	M040101	05060147330045	Medikit Elite Pack of 20 wasproof plaster - CASE OF 1000
346	506013188CE05ARE	M040101	05060131883465	Dependaplast Washproof Plasters Assorted Box of 120
446	506013188CE05ARE	M040101	05060131884462	Dependaplast Blue Plasters Assorted Box of 120
448	506013188CE05ARE	M040101	05060131884486	Dependaplast blue food area plasters 4cm x 2cm box of 100
449	506013188CE05ARE	M040101	05060131884493	Dependaplast blue food area plasters 6cm x 2cm box of 100
509	506013188CE05CRJ	M040101	05060131885094	Dependaplast Advanced fabric plasters 4cm x 2cm box of 100
510	506013188CE05CRJ	M040101	05060131885100	Dependaplast Advanced Fabric plasters assorted wallet of 10
511	506013188CE05CRJ	M040101	05060131885117	Dependaplast Advanced fabric plasters 4cm x 4cm box of 100
512	506013188CE05CRJ	M040101	05060131885124	Dependaplast Advanced fabric plasters 6cm x 2cm box of 100
513	506013188CE05CRJ	M040101	05060131885131	Dependaplast Advanced Fabric Plasters 7cm x 2cm box of 100
514	506013188CE05CRJ	M040101	05060131885148	Dependaplast Advanced Fabric Plasters 7.5cm x 2.5cm box of 100
515	506013188CE05CRJ	M040101	05060131885155	Dependaplast Advanced fabric plasters 7.5cm x 5cm box of 50
516	506013188CE05CRJ	M040101	05060131885162	Dependaplast Advanced Fabric Plasters Assorted box of 100
518	506013188CE05CRJ	M040101	05060131885186	Dependaplast Advanced Fabric Plasters Fingertip Box of 50
519	506013188CE05CRJ	M040101	05060131885193	Dependaplast Advanced Fabric Plasters Anchor Box of 50
520	506013188CE05CRJ	M040101	05060131885209	Dependaplast Advanced Fabric Plasters Assorted Wallet of 20
524	506013188CE05CRJ	M040101	05060131885247	Dependaplast multisoft plasters 7.5cm x 2.5cm box of 100
525	506013188CE05CRJ	M040101	05060131885254	Dependaplast multisoft plasters 7.5cm x 5cm box of 50
526	506013188CE05CRJ	M040101	05060131885261	Dependaplast multisoft plasters assorted box of 100
530	506013188CE05ARE	M040101	05060131885308	Dependaplast washproof plasters 4cm x 2cm box of 100
531	506013188CE05ARE	M040101	05060131885315	Dependaplast washproof plasters 4cm x 4cm box of 100
5311	506013188CE05ARE	M040101	05060186991740	Washproof Spot Plaster 2.2cm - Non Perforated Box of 100
532	506013188CE05ARE	M040101	05060131885322	Dependaplast washproof plasters 6cm x 2cm box of 100
533	506013188CE05ARE	M040101	05060131885339	Dependaplast washproof plasters 7cm x 2cm box of 100
534	506013188CE05ARE	M040101	05060131885346	Dependaplast washproof plasters 7.5cm x 2.5cm box of 100
535	506013188CE05ARE	M040101	05060131885353	Dependaplast washproof plasters 7.5cm x 5cm box of 50
536	506013188CE05ARE	M040101	05060131885360	Dependaplast washproof plasters assorted box of 100
538	506013188CE05ARE	M040101	05060131885384	Dependaplast washproof plasters fingertip box of 50

539	506013188CE05ARE	M040101	05060131885391	Dependaplast washproof plasters anchor box of 50
540	506013188CE05ARE	M040101	05060131885407	Dependaplast blue food area plasters assorted wallet of 20
541	506013188CE05ARE	M040101	05060131885414	Dependaplast blue food area plasters 4cm x 4cm box of 100
542	506013188CE05ARE	M040101	05060131885421	Dependaplast blue food area plasters assorted wallet of 10
543	506013188CE05ARE	M040101	05060131885438	Dependaplast blue food area plasters 7cm x 2cm box of 100
544	506013188CE05ARE	M040101	05060131885445	Dependaplast blue food area plasters 7.5cm x 2.5cm box of 100
545	506013188CE05ARE	M040101	05060131885452	Dependaplast blue food area plasters 7.5cm x 5cm Box 50
546	506013188CE05ARE	M040101	05060131885469	Dependaplast blue food area plasters assorted box of 100
548	506013188CE05ARE	M040101	05060131885483	Dependaplast blue food area plasters fingertip box of 50
549	506013188CE05ARE	M040101	05060131885490	Dependaplast blue food area plasters anchor box of 50
550	506013188CE05ARE	M040101	05060131885506	Dependaplast washproof spot plasters box of 100
551	506013188CE05ARE	M040101	05060131885513	Dependaplast washproof plasters assorted poly pack of 24
553	506013188CE05ARE	M040101	05060131885537	Dependaplast washproof plasters assorted wallet of 20
554	506013188CE05ARE	M040101	05060131885544	Dependaplast washproof plasters assorted wallet of 10
555	506013188CE05CRJ	M040101	05060131885551	Dependaplast Advanced Fabric Finger Extension Plasters Box of 50
557	506013188CE05ARE	M040101	05060131885575	Dependaplast Finger Extension Plasters Washproof Box of 50
558	506013188CE05ARE	M040101	05060131885582	Dependaplast Finger Extension Plasters Blue Box of 50
560	506013188CE05CRJ	M040101	05060131885605	Dependaplast Advanced Fabric Plasters 4cm x 2cm
561	506013188CE05CRJ	M040101	05060131885612	Dependaplast Advanced Fabric Plasters 4cm x 4cm
562	506013188CE05CRJ	M040101	05060131885629	Dependaplast Advanced Fabric Plasters 6cm x 2cm
563	506013188CE05CRJ	M040101	05060131885636	Dependaplast Advanced Fabric Plasters 7cm x 2cm
5630	506013188CE05ARE	M040101	05060738577781	Protect Childrens Washproof Plasters Assorted Box of 20
564	506013188CE05CRJ	M040101	05060131885643	Dependaplast Advanced Fabric Plasters 7.5cm x 2.5cm
565	506013188CE05CRJ	M040101	05060131885650	Dependaplast Advanced Fabric Plasters 7.5cm x 5cm
568	506013188CE05CRJ	M040101	05060131885681	Dependaplast Advanced Fabric Plasters Fingertip
569	506013188CE05CRJ	M040101	05060131885698	Dependaplast Advanced Fabric Plasters Anchor
1572	506013188CE05CRJ	M040101	05060497994430	Dependaplast multisoft plasters 6cm x 2cm - SINGLE
574	506013188CE05CRJ	M040101	05060131885742	Dependaplast multisoft plasters 7.5cm x 2.5cm
575	506013188CE05CRJ	M040101	05060131885759	Dependaplast multisoft plasters 7.5cm x 5cm
580	506013188CE05ARE	M040101	05060131885803	Dependaplast washproof plasters 4cm x 2cm
581	506013188CE05ARE	M040101	05060131885810	Dependaplast washproof plasters 4cm x 4cm
582	506013188CE05ARE	M040101	05060131885827	Dependaplast washproof plasters 6cm x 2cm
583	506013188CE05ARE	M040101	05060131885834	Dependaplast washproof plasters 7cm x 2cm
584	506013188CE05ARE	M040101	05060131885841	Dependaplast washproof plasters 7.5cm x 2.5cm
585	506013188CE05ARE	M040101	05060131885858	Dependaplast washproof plasters 7.5cm x 5cm
586	506013188CE05ARE	M040101	05060131885865	Dependaplast washproof plasters fingertip
587	506013188CE05ARE	M040101	05060131885872	Dependaplast washproof plasters anchor
588	506013188CE05ARE	M040101	05060131885889	Dependaplast washproof spot plasters
590	506013188CE05ARE	M040101	05060131885902	Dependaplast blue food area plasters 4cm x 2cm
591	506013188CE05ARE	M040101	05060131885919	Dependaplast blue food area plasters 4cm x 4cm
592	506013188CE05ARE	M040101	05060131885926	Dependaplast blue food area plasters 6cm x 2cm
593	506013188CE05ARE	M040101	05060131885933	Dependaplast blue food area plasters 7cm x 2cm
594	506013188CE05ARE	M040101	05060131885940	Dependaplast blue food area plasters 7.5cm x 2.5cm

595	506013188CE05ARE	M040101	05060131885957	Dependaplast blue food area plasters 7.5cm x 5cm
596	506013188CE05ARE	M040101	05060131885964	Dependaplast blue food area plasters fingertip
597	506013188CE05ARE	M040101	05060131885971	Dependaplast blue food area plasters anchor
626	506013188CE05ARE	M040101	05060131886268	Dependaplast blue detectable plasters assorted box of 40 (for BS8599-1 kits)
627	506013188CE05ARE	M040101	05060131886275	Dependaplast blue detectable plasters assorted box of 60 (for BS8599-1 kits)
633	506013188CE05ARE	M040101	05060131886336	Dependaplast childrens washproof plasters assorted box of 100
653	506013188CE05ARE	M040101	05060131886534	Dependaplast clear washproof plasters 7.5cm x 2.5cm
654	506013188CE05ARE	M040101	05060131886541	Dependaplast clear washproof plasters 4cm x 4cm
655	506013188CE05ARE	M040101	05060131886558	Dependaplast clear washproof plasters 7cm x 2cm
6632	506013188CE05ARE	M040101	05060497998735	Dependaplast Clear Washproof Plasters 6cm x 2cm
6634	506013188CE05ARE	M040101	05060497998476	Dependaplast Clear Washproof Plasters 7.5cm x 5cm
6934	506013188CE05ARE	M040101	05060497996885	Dependaplast Clear Washproof Plasters 7.5cm x 2.5cm Box of 100
6939	506013188CE05ARE	M040101	05060497996939	Dependaplast Clear Washproof Plasters Assorted Box of 100
6942	506013188CE05ARE	M040101	05060497996984	Dependaplast Clear Washproof Plasters 7.5cm x 5cm Box of 50
6944	506013188CE05ARE	M040101	05060885049810	Dependaplast washproof plasters 7cm x 2cm(10pcs)+anchor(5pcs)+fingertip (5pcs) in grip bag
907	506013188CE05ARE	M040101	05060131889078	Dependaplast washproof pilfer proof plasters box of 5 x 45
916	506013188CE05CRJ	M040101	05060131889160	Dependaplast fabric pilfer proof plasters box of 5 x 40
94334	506013188CE05CRJ	M040101	05032483000470	Rahmqvist Advanced Fabric Fingertip Pilfer Proof Plasters Wallet of 16 - Box of 5
94347	506013188CE05CRJ	M040101	05032483000487	Rahmqvist Advanced Blue Detectable Fabric Fingertip Pilfer Proof Plasters Wallet of 16 - Box of 5
94349	506013188CE05BRG	M040101	05032483000494	Businesscare Fabric PlastersTraditional Heavyweight 2cm x 12cm (Finger Extension) Box of 50
944	506013188CE05ARE	M040101	05060131889443	Dependaplast washproof plasters assorted box of 40 (for BS8599-1 kits)
946	506013188CE05ARE	M040101	05060131889467	Dependaplast washproof plasters assorted box of 60 (for BS8599-1 kits)
948	506013188CE05ARE	M040101	05060131889481	Dependaplast washproof plasters assorted box of 100 (for BS8599-1 kits)
984	506013188CE05ARE	M040101	05060131889849	Dependaplast blue detectable pilfer proof plasters box of 5 x 35
C065	506013188CE05BRG	M040101	05032483000500	Lifemarque Heavyweight Fabric Plasters Assorted Pack of 9
C077	506013188CE05ARE	M040101	05032483000517	Lifemarque Childrens Washproof Plasters Pack of 20
C407	506013188CE05ARE	M040101	05060151361783	Core Medical blue assorted plasters box of 100
C429	506013188CE05CRJ	M040101	05060151364623	Core Medical Advanced Fabric assorted plasters box of 100
F94021	506013188CE05ARE	M040101	05060203754808	St John Washproof Assorted Plasters Box of 100
F94025	506013188CE05ARE	M040101	05060203754846	St John Blue Detectable Assorted Plasters Wallet of 10
F94028	506013188CE05ARE	M040101	05060203754877	St John Blue Detectable Plasters 7.5cm x 2.5cm Box of 100
F94030	506013188CE05ARE	M040101	05060203754891	St John Washproof Plasters 7.5cm x 2.5cm Box of 100
LP516	506013188CE05CRJ	M040101	05060738578108	Lewis-Plast Assorted Fabric Plasters - Box of 100 (AMAZON)
LP536	506013188CE05ARE	M040101	05060738578092	Lewis-Plast Assorted Washproof Plasters - Box of 100 (AMAZON)
MS-8510	506013188CE05ARE	M040101	05065019646071	Mere Supplies washproof plasters assorted wallet of 20
RMD3082	506013188CE05ARE	M040101	05060265380205	Williams Medical Waterproof Spot Plasters (Ventilated) Box of 200
X0040	506013188CE05ARE	M040101	05060738578726	Baby Shark Washproof Plasters Assorted Box of 20
X0041	506013188CE05ARE	M040101	05060738578733	Baby Shark Washproof Plasters Assorted Wallet of 20
X1195	506013188CE05ARE	M040101	05032483000340	BCB Washproof Assorted Plasters Wallet of 20
X1196	506013188CE05ARE	M040101	05032483000357	BCB Washproof Assorted Plasters Wallet of 10
X1271	506013188CE05ARE	M040101	05060186993263	YPO Washproof Assorted Plasters - Box of 120
X1370	506013188CE05ARE	M040101	05060497998902	Red Cross NZ Washproof Plasters Assorted Box of 40
X1371	506013188CE05ARE	M040101	05060497998919	Red Cross NZ Washproof Plasters Assorted Wallet of 10

X1372	506013188CE05ARE	M040101	05060497998926	Red Cross NZ Washproof Plasters Assorted Wallet of 20
X1373	506013188CE05ARE	M040101	05060738578191	Red Cross NZ 'Here For Good' Washproof Plasters Assorted Wallet of 10
X1566	506013188CE05ARE	M040101	05060497999626	Red Cross NZ Washproof Plasters Assorted Box of 60
X1567	506013188CE05ARE	M040101	05060497999633	Red Cross NZ Washproof Plasters Assorted Box of 100
X1650	506013188CE05ARE	M040101	05060186999012	Arasca Washproof Plasters Assorted Wallet of 10
X2360	506013188CE05CRJ	M040101	050604979988391	Normad Advanced Fabric Plasters Assorted Pack of 10 (Grip Bag)
X2361	506013188CE05ARE	M040101	05060497998407	Normad Washproof Plasters Assorted Pack of 10 (Grip Bag)
X2390	506013188CE05CRJ	M040101	05023969278087	SCAN Fabric Plasters Assorted Box of 120
X2391	506013188CE05ARE	M040101	05023969278070	SCAN Blue Plasters Assorted Box of 120
X4661	506013188CE05ARE	M040101	05060497998643	Dependaplast Washproof Assorted Plasters Box of 120
X4662	506013188CE05ARE	M040101	05060497997134	Dependaplast Washproof Assorted Plasters Box of 150
X4663	506013188CE05ARE	M040101	05060497998650	Dependaplast Blue Food Area Plasters Assorted Box of 120
X4664	506013188CE05ARE	M040101	05060497998667	Dependaplast Blue Food Area Plasters Assorted Box of 150
X4665	506013188CE05CRJ	M040101	05060497998674	Dependaplast Advanced Fabric Plasters Assortment Box of 120
X4666	506013188CE05CRJ	M040101	05060497996960	Dependaplast Advanced Fabric Plasters Assortment Box of 150
X508	506013188CE05CRJ	M040101	05032483000364	Dependaplast Advanced Fabric Plasters 7.5cm x 2.5cm Pack of 30 (INT. SOS)
X520	506013188CE05CRJ	M040101	05032483000371	Rahmqvist Fabric Pfler Proof Plasters 5 x 40 (ARTNR94337)
X521	506013188CE05ARE	M040101	05032483000388	Rahmqvist Washproof Pfler Proof Plasters 5 x 45
X522	506013188CE05ARE	M040101	05032483000395	Rahmqvist Blue Detectable Pfler Proof Plaster 5 x 35
X5700	506013188CE05ARE	M040101	050601869994512	Pharmacare Childrens Plasters 6cm x 2cm - Box of 25 (PLAST06)
X5701	506013188CE05ARE	M040101	050601869994529	Pharmacare Washproof Plasters 7cm x 2cm - Box of 25 (PLAST04)
X5702	506013188CE05ARE	M040101	050601869994536	Pharmacare Clear Plasters 7cm x 2cm - Box of 25 (PLAST05)
X5707	506013188CE05BRG	M040101	050601869994543	Pharmacare Fabric Plasters Assorted - Box of 25 (RUBBER Z/O ADHESIVE) (PLAST02)
X5710	506013188CE05BRG	M040101	050601869997933	Pharmacare Fabric Stretch 7.5cm x 2.5cm Plasters - Box of 25 (PLAST07)
X5711	506013188CE05ARE	M040101	05060186997940	Pharmacare Spot Plaster - Box of 25 (Non Perforated) (PLAST08)
X5713	506013188CE05ARE	M040101	05060186999579	Pharmacare Blue Plasters 7cm x 2cm Box of 25 (PLAST09)
X5714	506013188CE05CRJ	M040101	05060186999586	Pharmacare Fabric Extension Plasters Box of 12 (PLAST10)
X6405	506013188CE05ARE	M040101	05060151360816	Coreplast blue food area plasters assorted wallet of 20 (C406)
X7470	506013188CE05ARE	M040101	05060497998100	St Andrews Washproof Assorted Plasters Wallet of 10
X7857	506013188CE05ARE	M040101	05060738579327	Mini First Aid Washproof Assorted Plasters Pack of 20
X7858	506013188CE05ARE	M040101	05060738579440	Mini First Aid Washproof Plasters Assortment of 46
X7859	506013188CE05ARE	M040101	05032483000401	Mini First Aid - Wallet of 5 Washproof Plasters 6cm x 2cm
X7974	506013188CE05ARE	M040101	05032483000418	Mini First Aid Plasters 6cm x 2cm - Wallet of 20
X8034	506013188CE05CRJ	M040101	05060885048073	Access Expedition Endurance Dependaplast Advanced Fabric Plasters 4cm x 4cm Pack of 4
X8035	506013188CE05CRJ	M040101	05060885048066	Access Expedition Endurance Dependaplast Advanced Fabric Plasters 7.5cm x 2.5cm Pack of 4
X9697	506013188CE05ARE	M040101	05060497994720	Reliance Blue Assorted Plasters Box of 150