

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, Kylemore 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-04-00, version 3A.

Signed:

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



Date:

2024.06.13

Place:

Shanghai, China



Product REF	Basic UDI-DI	EMDN	UDI-DI	Product Description
2765	506013188CE04XK	M040401	05060186991306	Reliwipe Blue Saline Wipes Box of 20 (for BS8599-1 kits)
2766	506013188CE04XK	M040401	05060186991313	Reliwipe Blue Saline Wipes Box of 30 (for BS8599-1 kits)
714	506013188CE04XK	M040401	05060131887142	Reliwipe Moist Cleansing Alcohol Free Wipes Blue Box of 100
714S	506013188CE04XK	M040401	05060497997707	Reliwipe Moist Cleansing Alcohol Free Wipes Blue (Single)
740	506013188CE04XK	M040401	05060131887401	Reliwipe moist saline cleansing wipes sterile pack of 10
745	506013188CE04XK	M040401	05060131887456	Reliwipe moist saline cleansing wipes sterile box of 100
759	506013188CE04XK	M040401	05060738570379	Medikids Moist Saline Cleansing Wipes Sterile Box of 100
759S	506013188CE04XK	M040401	05060738570379	Medikids Moist Saline Cleansing Wipes Sterile - Single
77894	506013188CE04XK	M040401	150324830000422	Medikit Saline cleaning wipe box of 100 (plain white box) - CASE OF 20
939	506013188CE04XK	M040401	05060131889399	Reliwipe moist cleansing wipes box of 20 (for BS8599-1 kits)
945	506013188CE04XK	M040401	05060131889450	Reliwipe moist cleansing wipes box of 30 (for BS8599-1 kits)
94635-5	506013188CE04XK	M040401	050324830000432	Businesscare Saline Cleansing Wipes Box of 50
94635-S	506013188CE04XK	M040401	050324830000449	Businesscare Saline Cleansing Wipe
LP745	506013188CE04XK	M040401	05060738578115	Lewis-Plast Sterile Saline Moist Cleansing Wipes - Box of 100 (AMAZON)
LP746	506013188CE04XK	M040401	05060885048448	Lewis-Plast Sterile Saline Moist Cleansing Wipes - Box of 200 (AMAZON)
MS-8502	506013188CE04XK	M040401	05065019646026	Mere Supplies Wound Wipes Box of 100
STR18	506013188CE04XK	M040401	55060885049310	Eurekaplast - Sterile Saline Moist Cleaning Wipes - Individually Wrapped - Box of 100
STR19	506013188CE04XK	M040401	55060885049334	Value Aid - Sterile Saline Moist Cleaning Wipes - Individually Wrapped - Box of 100
X1390	506013188CE04XK	M040401	05060497998940	Red Cross NZ Moist Cleansing Wipes Box of 20
X1565	506013188CE04XK	M040401	05060497999619	Red Cross NZ Cleansing Wipes Box of 30
X2362	506013188CE04XK	M040401	05060497998414	Nomad Moist Saline Cleansing Wipes Sterile Pack of 10 (Grip Bag)
X5712	506013188CE04XK	M040401	05060186997957	Pharmacare Wound Cleansing Wipes - Box of 10
X6335	506013188CE04XK	M040401	05060151360755	Corewipe moist saline cleansing wipes (C310) - Box of 100

Document Approval Record

RM-007442-DC - Ver 1

Reliance Medical (Shanghai) Co., Ltd. - Saline Wipes - Declaration of Conformity - EU - MDR
(2017/745)
Author: Jason Lo

Approval Detail:

Approver	Location/Time
Jason Lo	Talke, UK - Wed 26th Mar 2025 - 08:19
Role	ID/Checksum
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3rd Party Document Accepted for Use by RM	

Approval History:

Version	Approval Date	Approved By	Checksum
1	Wed Mar 26 2025	Jason Lo	fba87a0bbadda25eb212a358277c6c86