



**DECLARATION DE CONFORMITE UE CONFORMEMENT A L'ARTICLE 19 ET
AUX ANNEXES II ET III DU REGLEMENT (UE) 2017/745,**

**EU DECLARATION OF CONFORMITY IN ACCORDANCE
WITH THE ARTICLE 19 AND ANNEX III AND II OF THE REGULATION (EU) 2017/745**

LCH Medical Products, 12-14 rue Sarah Bernhardt – 92600 Asnières-sur-Seine – FRANCE,
Assurons et déclarons sous notre seule responsabilité que les dispositifs médicaux /
Certify and declare under our sole responsibility that the medical devices:

GANTS VINYL non stériles à usage unique, *Disposable non sterile GLOVES,*

SAP REFERENCE	SAGE REFERENCE	ITEM	UDI-DI Box	UDI-DI Carton
79506	SMX-00	Sensimax - White - Disposable ambidextrous synthetic examination gloves, non sterile, powder free - Size XS (5/6)	370 014 940 025 5	370 014 940 315 7
44572	SMX-01	Sensimax - White - Disposable ambidextrous synthetic examination gloves, non sterile, powder free - Size S (6/7)	370 014 940 026 2	370 014 940 316 4
44573	SMX-02	Sensimax - White - Disposable ambidextrous synthetic examination gloves, non sterile, powder free - Size M (7/8)	370 014 940 027 9	370 014 940 317 1
44574	SMX-03	Sensimax - White - Disposable ambidextrous synthetic examination gloves, non sterile, powder free - Size L (8/9)	370 014 940 028 6	370 014 940 318 8
44575	SMX-04	Sensimax - White - Disposable ambidextrous synthetic examination gloves, non sterile, powder free - Size XL (9/10)	370 014 940 029 3	370 014 940 319 5
30184	VNL-01	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, lightly powdered - Size S (6/7)	370 014 940 001 9	370 014 940 301 0
30185	VNL-02	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, lightly powdered - Size M (7/8)	370 014 940 002 6	370 014 940 302 7
30186	VNL-03	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, lightly powdered - Size L (8/9)	370 014 940 003 3	370 014 940 303 4
30187	VNL-04	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, lightly powdered - Size XL (9/10)	370 014 940 004 0	370 014 940 304 1
44576	VNX-00	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, powder free - Size XS (5/6)	370 014 940 040 8	370 014 940 320 1

MC



44577	VNX-01	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, powder free - Size S (6/7)	370 014 940 041 5	370 014 940 321 8
44578	VNX-02	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, powder free - Size M (7/8)	370 014 940 042 2	370 014 940 322 5
44579	VNX-03	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, powder free - Size L (8/9)	370 014 940 043 9	370 014 940 323 2
44580	VNX-04	Sensinyl - Transparent - Disposable ambidextrous vinyl examination gloves, non sterile, powder free - Size S (9/10)	370 014 940 044 6	370 014 940 324 9

Répondent aux exigences générales de sécurité et performance et aux recommandations du Règlement (UE) 2017/745

Are in conformity with the General Safety and Performance Requirements of the Regulation (EU) 2017/745.

Les dispositifs médicaux appartiennent à la classe I suivant la règle 1 de l'Annexe VIII du Règlement (UE) 2017/745,

Medical device belong to class I according to the rule 1 of Annex VIII of the Regulation (EU), 2017/745

Lieu et date d'émission / *Place and date of issue*

Asnières-sur-Seine, 10/06/2021

Par/by Marie CARRIERE

Personne chargée de veiller au respect de la Réglementation (PCVRR)/ *Person responsible for regulatory compliance (PRRC)*