

**DECLARATION UE DE CONFORMITE 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 ANNEXES II AND III OF THE REGULATION (EU) 2017/745**

LCH Médical 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:*

**Masques à usage Médical Aerokyn, *Aerokyn Medical-grade face masks***

- **Basic UDI-DI : 37001494NSMEDICALMASKJM**

SAP REFERENCE	SAGE REFERENCE	ITEM	UDI-DI Box	UDI-DI Carton
35533	PLM-01	High filtration medical face masks AEROKYN Mask type II / Earloops / 3 plies	370 014 940 100 9	370 014 940 120 7
35531	PLM-02	High filtration medical face masks AEROKYN Mask type II / Laces / 3 plies	370 014 940 101 6	370 014 940 121 4
79460	PLM-01R	Medical grade ultrafiltration face masks with protection against liquid projections AEROKYN mask type IIR / Earloops / 3 plies	370 014 940 109 2	370 014 940 129 0
79461	PLM-02R	Medical grade ultrafiltration face masks with protection against liquid protections Type IIR / Laces / 3 plies	370 014 940 110 8	370 014 940 140 5
79463	PLM-04R	Medical-grade ultrafiltration face mask with visor for protection against liquid projections VISIO AEROKYN mask type IIR / Earloops / 3 plies	370 014 940 166 5	370 014 940 167 2
79458	PLM-01E	Disposable face masks for medical use AEROKYN mask type II / Earloops / Childs / 3 plies	370 014 940 108 5	370 014 940 128 3
70026	NA	Medical face masks so called « care masks » AEROKYN Mask type I / Earloops / 3 plies	370 014 940 195 5	370 014 294 0196 2

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

*Medical devices 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, 15/06/2021

Par/by Marie CARRIERE

Personne en charge des aspects réglementaires / *Person responsible for regulatory compliance*

