

[CLIENT]  
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Rueil-Malmaison, le 16 novembre 2022,

## AVIS DE SECURITE (FSN) URGENT

**Référence** : FSN16112022AERYS

**Nom commercial du dispositif médical** : AERYS

**Fabricant** : WINNCARE France

**Contact national (information)** : WINNCARE France

**FSCA-Identification** : Product Field Action : **R2230714**

**Type d'action** : Field Safety Corrective Action : Action qualité\_MV

**Dispositifs concernés (SN)** : Cf. la liste des numéros de série concernés en annexe de l'avis.

Madame, Monsieur,

Suite à une réclamation de l'un de nos clients nous avons identifié un risque de perte de performance de la fonction de freinage de certains lits médicaux du modèle AERYS fabriqués et commercialisés entre le 13 avril 2021 et le 13 septembre 2021 inclus.

L'analyse des causes a montré qu'une situation pouvait survenir lorsque le lit AERYS freiné est soumis à la conjonction d'une charge verticale et d'un déplacement latéral volontaire et forcé (poussée/traction) et les roues se trouvant dans le sens du déplacement. Si cela constitue une erreur d'utilisation en regard de l'emploi prévue, ce scénario reste possible.

Nous avons interrompu la commercialisation du produit concerné le 14 septembre 2021.

Actions préventives : signaler la diminution de la performance du freinage à notre service après-vente (réclamation).

Actions correctives : Remplacement du système de freinage centralisé de tous les lits médicaux concernés.





Nous faisons le nécessaire pour vous réduire a minima le risque que pourrait représenter cette situation.

L'ANSM est informée de cette mesure de sécurité.

Nous vous remercions de votre confiance.

Comité Matériovigilance WINNCARE

Dossier suivi par :

Philippe ESPINASSE, Directeur Affaires règlementaires et médical.

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Sébastien CHEVILLON, Responsable SAV France.

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## FORMULAIRE DE REPONSE CLIENT

### Informations Produit

Référence FSN	FSN16112022AERY5
Date FSN	
Référence produit	
Numéro(s) <sup>1</sup> de série	

### Informations Client distributeur (PSDM)

Numéro Client	
Nom de l'organisme	
Adresse	
Nom du contact	
Titre ou fonction	
Numéro de téléphone	
E-mail	

### Information Client Etablissement de santé ou médico-social

Numéro FINESS	
Nom de l'établissement	
Adresse	
Nom du contact	
Titre ou fonction	
Numéro de téléphone	
E-mail	

<sup>1</sup> Lorsque l'intervention technique réalisée un même jour concerne plusieurs lits AERY5 dans un même établissement alors un seul formulaire pourra être utilisé et les numéros de série renseignés sur le même document.



**Actions menées par le fabricant ou le Client distributeur (PSDM) dans l'Etablissement**

(Cocher la cellule de la colonne de gauche)

	J'accuse réception de cet avis de sécurité et je confirme l'avoir lu et compris
	J'ai mis en place toutes les actions demandées par cet avis de sécurité
	Les informations de cet avis de sécurité ont été communiquées à tous les utilisateurs concernés et les mesures préventives ont été mises en œuvre.
	J'ai remplacé le système de freinage centralisé par le nouveau
	J'ai contrôlé le bon fonctionnement du nouveau freinage centralisé
	J'ai transmis les pièces remplacées au SAV de la société WINNCARE France

**Validation et approbation**

Date de l'intervention technique	
Nom et Prénom du technicien (Majuscules)	
Signature	
Représentant de l'établissement (exploitant)	
Signature	
Tampon	

Accusé de réception à retourner avec le rapport d'intervention technique

**Service SAV – WINNCARE France**  
**4, Le Pas du Château, 85670 Saint-Paul-Mont-Penit**  
 e-mail : [sav@winnccare.fr](mailto:sav@winnccare.fr) ; n° téléphone : 02 51 98 39 24



FR032104/02680	FR032104/03505	FR032104/04028	FR032104/04475	FR032104/04959
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FR032107/07519	FR032107/07562	FR032107/07605	FR032108/00609	FR032108/04214
FR032107/07520	FR032107/07563	FR032107/07606	FR032108/00610	FR032108/04215
FR032107/07521	FR032107/07564	FR032107/07607	FR032108/00611	FR032108/04216
FR032107/07522	FR032107/07565	FR032107/07608	FR032108/00617	FR032108/04217
FR032107/07523	FR032107/07566	FR032107/07609	FR032108/00622	FR032108/04218
FR032107/07524	FR032107/07567	FR032107/07610	FR032108/02176	FR032108/04219
FR032107/07525	FR032107/07568	FR032107/07611	FR032108/02178	FR032108/04220
FR032107/07526	FR032107/07569	FR032107/07612	FR032108/02181	FR032108/04221
FR032107/07527	FR032107/07570	FR032107/07613	FR032108/02216	FR032108/04222
FR032107/07528	FR032107/07571	FR032107/07614	FR032108/02219	FR032108/04223
FR032107/07529	FR032107/07572	FR032107/07615	FR032108/02245	FR032108/04224
FR032107/07530	FR032107/07573	FR032107/07616	FR032108/02375	FR032108/04501
FR032107/07531	FR032107/07574	FR032107/07617	FR032108/02376	FR032108/04502
FR032107/07532	FR032107/07575	FR032107/07618	FR032108/02377	FR032108/04503
FR032107/07533	FR032107/07576	FR032107/07619	FR032108/02378	FR032108/04504
FR032107/07534	FR032107/07577	FR032107/07620	FR032108/02379	FR032108/04505



FR032108/04506	FR032108/05472	FR032108/05855	FR032108/07030	FR032109/00488
FR032108/04507	FR032108/05473	FR032108/05856	FR032108/07031	FR032109/00489
FR032108/04746	FR032108/05474	FR032108/05857	FR032108/07123	FR032109/00490
FR032108/04747	FR032108/05475	FR032108/05858	FR032108/07124	FR032109/00491
FR032108/04748	FR032108/05476	FR032108/06374	FR032108/07125	FR032109/00492
FR032108/04749	FR032108/05477	FR032108/06375	FR032108/07126	FR032109/00760
FR032108/04750	FR032108/05478	FR032108/06376	FR032108/07127	FR032109/00761
FR032108/04751	FR032108/05479	FR032108/06377	FR032109/00123	FR032109/00762
FR032108/04752	FR032108/05820	FR032108/06378	FR032109/00124	FR032109/00763
FR032108/04753	FR032108/05821	FR032108/06379	FR032109/00125	FR032109/00764
FR032108/05439	FR032108/05822	FR032108/06380	FR032109/00126	FR032109/00765
FR032108/05440	FR032108/05823	FR032108/06381	FR032109/00127	FR032109/00766
FR032108/05441	FR032108/05824	FR032108/06382	FR032109/00128	FR032109/00767
FR032108/05442	FR032108/05825	FR032108/06383	FR032109/00129	FR032109/00768
FR032108/05443	FR032108/05826	FR032108/06384	FR032109/00130	FR032109/00769
FR032108/05444	FR032108/05827	FR032108/06385	FR032109/00131	FR032109/00770
FR032108/05445	FR032108/05828	FR032108/06386	FR032109/00132	FR032109/00771
FR032108/05446	FR032108/05829	FR032108/06387	FR032109/00133	FR032109/00772
FR032108/05447	FR032108/05830	FR032108/06388	FR032109/00134	FR032109/00773
FR032108/05448	FR032108/05831	FR032108/06389	FR032109/00135	FR032109/00774
FR032108/05449	FR032108/05832	FR032108/06390	FR032109/00136	FR032109/00775
FR032108/05450	FR032108/05833	FR032108/06391	FR032109/00137	FR032109/00776
FR032108/05451	FR032108/05834	FR032108/06392	FR032109/00138	FR032109/00777
FR032108/05452	FR032108/05835	FR032108/06393	FR032109/00139	FR032109/00778
FR032108/05453	FR032108/05836	FR032108/06394	FR032109/00140	FR032109/00779
FR032108/05454	FR032108/05837	FR032108/07012	FR032109/00141	FR032109/00780
FR032108/05455	FR032108/05838	FR032108/07013	FR032109/00142	FR032109/00781
FR032108/05456	FR032108/05839	FR032108/07014	FR032109/00143	FR032109/00782
FR032108/05457	FR032108/05840	FR032108/07015	FR032109/00144	FR032109/00783
FR032108/05458	FR032108/05841	FR032108/07016	FR032109/00145	FR032109/00784
FR032108/05459	FR032108/05842	FR032108/07017	FR032109/00146	FR032109/00785
FR032108/05460	FR032108/05843	FR032108/07018	FR032109/00147	FR032109/00786
FR032108/05461	FR032108/05844	FR032108/07019	FR032109/00247	FR032109/00787
FR032108/05462	FR032108/05845	FR032108/07020	FR032109/00391	FR032109/00788
FR032108/05463	FR032108/05846	FR032108/07021	FR032109/00392	FR032109/00789
FR032108/05464	FR032108/05847	FR032108/07022	FR032109/00393	FR032109/00790
FR032108/05465	FR032108/05848	FR032108/07023	FR032109/00394	FR032109/00791
FR032108/05466	FR032108/05849	FR032108/07024	FR032109/00395	FR032109/00792
FR032108/05467	FR032108/05850	FR032108/07025	FR032109/00457	FR032109/00793
FR032108/05468	FR032108/05851	FR032108/07026	FR032109/00458	FR032109/00794
FR032108/05469	FR032108/05852	FR032108/07027	FR032109/00459	FR032109/00795
FR032108/05470	FR032108/05853	FR032108/07028	FR032109/00460	FR032109/00796
FR032108/05471	FR032108/05854	FR032108/07029	FR032109/00461	FR032109/00797



