

DECLARATION OF CONFORMITY DÉCLARATION DE CONFORMITÉ DICHIARAZIONE DI CONFORMITA'

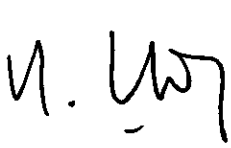
Directive / Direttiva : 93/42/CEE

<ul style="list-style-type: none"> ▪ Device type, class Type d'appareil, classe Tipo di pompa, classe 	<ul style="list-style-type: none"> <i>Racking holders, Class I</i> Supports d'empilage, Classe I supporti, Classe I
<ul style="list-style-type: none"> ▪ Brand / Marque / Marca 	<ul style="list-style-type: none"> Fresenius Vial
<ul style="list-style-type: none"> ▪ Designation and serial numbers Désignation et numéros de série Designazione del tipo e numero di serie 	<ul style="list-style-type: none"> LINK 4 / LINK 4 + / LINK 6 / LINK 6 + AGILIA <i>From serial numbers / depuis le numéro de série / Tutti i numeri di serie dal</i> 1920 0001
<ul style="list-style-type: none"> Accessories, all lot numbers Accessoires, tous numéros de lot Accessori, tutti numeri di lotto 	<ul style="list-style-type: none"> <i>Agilia range accessories / Accessoires Gamme Agilia / Accessori di Gamma Agilia :</i> - <i>Supply and communication cables / Cordons d'alimentation et de communication /</i> <i>Cavi di alimentazione elettrica e di comunicazione</i> NURSE CALL AGILIA, DUO AGILIA, Y DUO, RS232 CABLE FOR AGILIA, DC-DC CONVERTER AGILIA, USB CABLE FOR AGILIA, VIGILANT® ETHERNET CABLE FOR AGILIA
<ul style="list-style-type: none"> Compatible devices Dispositifs compatibles Dispositivi compatibili 	<ul style="list-style-type: none"> Injectomat AGILIA
<ul style="list-style-type: none"> ▪ Manufacturer / Fabricant / Fabbrikante 	<ul style="list-style-type: none"> Fresenius Vial - Le Grand Chemin - 38590 BREZINS (France) Tel : +33 (0)4 76 67 10 10 - Fax : +33 (0)4 76 65 56 66
<ul style="list-style-type: none"> ▪ Standards / Normes / Normative 	<ul style="list-style-type: none"> CEI 60 601-1 <i>MEDICAL ELECTRICAL EQUIPMENT : GENERAL REQUIREMENTS FOR SAFETY</i> <i>APPAREILS ELECTROMEDICAUX : REGLES GENERALES DE SECURITE</i> CEI 60 601-1-2 <i>MEDICAL ELECTRICAL EQUIPMENT : GENERAL REQUIREMENTS FOR SAFETY - 2. Collateral standard :</i> <i>electromagnetic compatibility</i> <i>APPAREILS ELECTROMEDICAUX - PARTIE 1 : REGLES GENERALES DE SECURITE -2. Norme</i> <i>collatérale : compatibilité électromagnétique</i> CEI 60 601-1-4 <i>MEDICAL ELECTRICAL EQUIPMENT : GENERAL REQUIREMENTS FOR SAFETY -- 4. Collateral</i> <i>standard : programmable electromedical devices</i> <i>APPAREILS ELECTROMEDICAUX : REGLES GENERALES DE SECURITE - 4. Norme collatérale : système</i> <i>électromédicaux programmables</i>
<ul style="list-style-type: none"> ▪ Technical file / Dossier Technique / Manuale tecnico 	<ul style="list-style-type: none"> DT0053

As legal representative of the manufacturer within the EEC, I declare under our own responsibility that the above products are in conformity with the essential requirements of the above mentioned directives and specifically Annex VII of the MD directive 93/42 EEC.

En tant que fabricant et représentant légal du fabricant établi dans la CEE, je déclare sous notre propre responsabilité que les produits ci-dessus sont conformes aux exigences essentielles des Directives mentionnées et particulièrement à l'annexe VII de la Directive 93/42CEE.

Essendo fabbricante/rappresentante legale del fabbricante stabilito nella CEE, dichiariamo sotto la nostra propria responsabilità che la pompa conforme ai dati inclusi nel manuale tecnico come pure alle esigenze essenziali delle Direttive citate sopra e più particolarmente all'allegato VII della Direttiva 93/42 EEC.



BREZINS, 03 avril 2006

Michel MONIER

Quality and Regulatory Affairs Manager / Directeur Qualité et Affaires Réglementaires
Direttore Qualità e per la regolamentazione