

DECLARATION OF CONFORMITY

Adriaanse Import en Export B.V.
Adriaan Mulderweg 9-11
Eindhoven - the Netherlands

Declares under sole responsibility that the following product

Item number: 05925
GTIN: 8711252059259

Description: VIVAMORE - Upper Back Straight Holder 2as

Picture of the item.



The described object of the declaration is in conformity with the relevant Union harmonisation legislation:

Directive or regulation
93/42/EC Medical devices directive (MDD)
EC 1907/2006 REACH
94/62/EC Packaging and Packaging waste
2001/95/EC General product safety directive

References to the relevant harmonized standards used or references to the specifications in relation to which conformity is declared:

EN 13485:2016
EN ISO 9001:2015

Signed for and on behalf of:

Adriaanse Import en Export B.V.
Eindhoven, 02-06-2022

I. Huntjens
Quality Manager

A handwritten signature in black ink, appearing to read 'I. Huntjens', is written over the printed name and title. The signature is fluid and cursive.

VERKLARING VAN OVEREENSTEMMING

DECLARATION OF CONFORMITY

Adriaanse Import en Export B.V.
Adriaan Mulderweg 9-11
Eindhoven - the Netherlands

Verklaart hierbij dat de volgende producten:

Declares under sole responsibility the following product

Artikelnummer: 05925

GTIN: 8711252059259

Beschrijving: VIVAMORE - Rechte houder voor de bovenrug

Description: Upper Back Straight Holder 2as

Foto van het artikel *Picture of the item*



Het beschreven voorwerp is in overeenkomst met de desbetreffende harmonisatiewetgeving van de Unie:

The described object of the declaration is in conformity with the relevant Union harmonisation legislation:

Richtlijn of verordening: *Directive or regulation:*

93/42/EG Richtlijn medische hulpmiddelen (MDD)

EC 1907/2006 REACH

94/62/EG Verpakking en verpakkingsafval

2001/95/EG Algemene richtlijn productveiligheid

Verwijzingen naar de toegepaste relevante geharmoniseerde normen of van de specificaties in verband waarmee de verklaring van overeenstemming :

References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

EN 13485:2016

EN ISO 9001:2015

Ondertekend voor en namens :

Signed for and on behalf of:

Adriaanse Import en Export B.V.
Eindhoven, 02-06-2022

I. Huntjens

Quality Manager



Konformitätserklärung

DECLARATION OF CONFORMITY

Adriaanse Import en Export B.V.
Adriaan Mulderweg 9-11
Eindhoven - the Netherlands

Erklärt in alleiniger Verantwortung das folgende Produkt

Declares under sole responsibility the following product

Artikelnummer: 05925

GTIN: 8711252059259

Beschreibung: VIVAMORE - Geradehalter für oberen Rücken

Description: Upper Back Straight Holder 2as

Foto des Artikels *Picture of the item*



Der Artikel wie beschrieben ist konform mit den einschlägigen Harmonisierungsrechtsvorschriften der Union:

The described object of the declaration is in conformity with the relevant Union harmonisation legislation:

Richtlinie oder Verordnung: *Directive or regulation:*

93/42/EWG Medizinprodukte -Richtlinie (MDD)

EC 1907/2006 REACH

94/62/EG Verpackungen und Verpackungsabfälle

2001/95/EG Allgemeine Produktsicherheitsrichtlinie

Verweise auf die einschlägigen harmonisierten Normen oder Bezugnahme auf Spezifikationen in Bezug auf die Konformität erklärt wird :

References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

EN 13485:2016

EN ISO 9001:2015

Unterzeichnet für und im Auftrag von:

Signed for and on behalf of:

Adriaanse Import en Export B.V.
Eindhoven, 02-06-2022

I. Huntjens
Quality Manager

A handwritten signature in black ink that reads 'I. Huntjens'. The signature is written in a cursive style and is positioned over the printed name and title.

DÉCLARATION DE CONFORMITÉ

DECLARATION OF CONFORMITY

Adriaanse Import en Export B.V.
Adriaan Mulderweg 9-11
Eindhoven - the Netherlands

Déclare sous sa seule responsabilité les produits suivants

Declares under sole responsibility the following product

Numéro d'objet: 05925

GTIN: 8711252059259

Description: VIVAMORE - Maintien du haut du dos

Description: Upper Back Straight Holder 2as

Photo de l'article *Picture of the item*



L'objet de la déclaration décrit ci-dessus est conforme à la législation d'harmonisation de l'Union applicable:

The described object of the declaration is in conformity with the relevant Union harmonisation legislation:

Directive ou d'un règlement: *Directive or regulation:*

93/42/CE directive sur les dispositifs médicaux (MDD)

EC 1907/2006 REACH

94/62/CE Emballages et déchets d'emballage

2001/95/CE directive générale de sécurité des produits

Références des normes harmonisées pertinentes appliquées ou des spécifications par rapport auxquelles la conformité est déclarée:

References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

EN 13485:2016

EN ISO 9001:2015

Signé pour et au nom de :

Signed for and on behalf of:

Adriaanse Import en Export B.V.
Eindhoven, 02-06-2022

I. Huntjens
Quality Manager

A handwritten signature in black ink, appearing to read 'I. Huntjens', is written over the printed name and title. The signature is fluid and cursive.