CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

>Return address: PO Box 16114, 2500 BC The Hague

Crestec Europe B.V.
Attn. Mr MPP Lemmens
Teleportboulevard 110
1043EJ Amsterdam

Date: 28 October 2014
Subject: registration medical device Class 1

Dear Mr Lemmens,

I hereby confirm the reception on 22 October 2014 of the notice under Article 5 of the Dutch Medical Devices Decree (BMH), concerning the placement of below-mentioned medical device Class 1 on the European market under the company name of IWASHOUORIMONO Co. Ltd., with Crestec Europe B.V. as Authorised Representative in Europe.

The product has been registered as medical device Class 1 under the following number, which needs to be mentioned in any further correspondence:

Foot Support

ASHIPITA
(NL-CA002-2014-32915)

Future changes in the above information, including potential changes in the categorization of risk classes, related to modifications of European regulations on the classification of medical devices, as well as to advancing scientific insights (ref. art. 9, par. 3 of Directive 93/42/EEC) need to be communicated by you, if applicable.

Farmatec

Visitor address:
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Inquiries:
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Our reference:
CIBG/Farma/20142444

Annex:
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Your request:
22 October 2014

The CIBG is an executive organization of the Ministry of Health, Welfare and Sport

Correspondence should only be directed to the return address, mentioning the date and the reference of this letter.

Notification of medical devices implies that the manufacturer, HearMEC Co., Ltd, has affixed the CE conformity marking on the concerned product before marketing it in any EU member state. As such, Crestec Europe B.V. guarantees that the medical device complies with the essential requirements stated in Directive 93/42/EEC and the BMH.

For completeness, we inform you that notwithstanding your notification, it is prohibited to have or deliver a medical device in case rules for this medical device are not followed or if there is no compliance with the Dutch Act on Medical Devices (WMH).
Please note in particular the Dutch language requirement as applicable in the Netherlands, the obligation to keep the technical documentation at your disposal and the obligation to have a post-market surveillance and vigilance system in place.

To conclude, I note that your notification of the delivery of the above product is just an administrative action. This confirmation of reception does not contain any qualification of the product at hand as a medical device in terms of art. 1 of WMH, nor about the categorization in risk class 1.

The Minister of Health, Welfare and Sport,
On behalf of her,
Farmatec | CIBG

Mr. Dr. M.J. van de Velde, MBA
Head of the cluster Farma