

PT PHC Indonesia National or Regional Regulation Certification/Registration



Registered
Establishment &
Device



Certified E.U.
Medical
Directory



Certified
Product Safety



US FDA

Registration Information

Facility Address: KANAGAWA INDUSTRIAL MEDICAL BUILDING, CHIKUBA-SHINYO BLDG., JAPAN Bldg., 1720, INDONESIA

Owner/Operator: PT PHC INDONESIA, KANAGAWA INDUSTRIAL MEDICAL BUILDING, CHIKUBA-SHINYO BLDG., JAPAN Bldg., 1720, INDONESIA

Official Correspondent: CHENHAI CHEN, PT PHC INDONESIA, KANAGAWA INDUSTRIAL MEDICAL BUILDING, CHIKUBA-SHINYO BLDG., JAPAN Bldg., 1720, INDONESIA

U.S. Agent: STEVEN HUBBARD, PHC CORPORATION OF NORTH AMERICA, 1700 UNIVERSITY PLACE, #100, ALABAMA, JAPAN Bldg., 1720, INDONESIA

Expiration Date: 2019-12-31

Certificate

Certificate No.: CU 72102714 02

MDD

For report no.: UNAN 3100027 004

Client Reference: KANAGAWA, KANAGAWA

Certified Product: Hearing Aid

Appendix: 1, 1-4

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3

U.S. and Canada

Manufacturer: Panasonic Healthcare Co., Ltd., 600 Seado-cho, Tsutsui-ku, Yokohama, KANAGAWA 224-8539, JAPAN

Scope: Manufacture of Hearing Aid

Date of Expiry: 03-03-2025

登録番号 001800020
Number of registration

医療機器 外国製造業者登録証
Registration certificate of foreign medical device manufacturer

Japan MHLW

製造者の名称: PT Panasonic Healthcare Indonesia

製造者の所在地: Kasean Industri ME100 Blok 9-1 Cikarang Barat, Bekasi 17520, INDONESIA

平成 28 年 4 月 22 日
2016 Year Month Day



Certified
Product Safety



Certified
Factory



Compliance
Certified

中国国家强制性产品认证证书

证书编号: 201301080930486

China CQC

松下健康医疗器械株式会社
生产企业的地址: PT. Panasonic Healthcare Indonesia, Kasean Industri ME100 Blok 9-1 Cikarang Barat, Bekasi 17520, 印度尼西亚

产品型号和系列: 规格: 型号

产品标准和技术要求: GB8898-2011; GB18307-2012; GB16725.1-2012

发证日期: 2014年08月08日 有效期至: 2018年07月24日

中国质量认证中心

인허가번호: KTC-088-10002

의료기기 제조 및 품질관리 기준 적합인정서

Korea FDA

제품명: Hearing Aid

제조업체: PT. Panasonic Healthcare Co., Ltd.

한국시험인증

QPS Evaluation Services Inc.

Testing, Certification and Field Evaluation Body

Canada QPS

Project Number: UR1296-6

Product: Hearing Aid

Model Number: MR-H203-PA, MR-H105-PA

Factory: PT Panasonic Healthcare Indonesia, Kasean Industri ME100 Blok 9-1 Cikarang Barat Bekasi 17520 Indonesia

Statement of Compliance: The products identified in this Certificate and described in the Report covered under the above referenced project number have been investigated and found to be in compliance with the relevant requirements of the above referenced standards.