

Declaration of Conformity

Manufacturer: PHU Technomex Sp. z o.o.
Ul. Szparagowa 15
44-141 Gliwice
Poland

We declare under our sole responsibility that

the medical device: **BATHTUBS FOR WHIRLPOOL MASSAGE OF
LOWER LIMBS**

models: **PIZARRO, PIZARRO BASIC**

serial number

**of class: IIa , rule 9 according to Annex IX of 93/42/EEC directive
Included in the technical files shall comply with the applicable essential requirements
and provisions of the directive 93/42/EEC and the Medical Devices Act of 20 May 2010
and related regulations of the Minister of Health.**

Conformity assessment procedure: Annex V of 93/42/EEC directive

Notified Body: TÜV Rheinland LGA Product GmbH (No 0197)
Tillystraße 2, 90431 Nürnberg, Germany



DYREKTOR
JANUSZ FRANCIK

Gliwice, 01.03.2012 r.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
P.H.U. TECHNOMEX Sp. z o.o.
ul. Szparagowa 15
44-141 Gliwice
Poland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, production, distribution,
installation and servicing of rehabilitation
and physical therapy devices**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60084022 0001

An audit was performed. Report No.: 26300170 002

This Certificate is valid until: 12.03.2018



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 13.03.2013

Certification Body



D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

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TÜV Rheinland LGA Products GmbH

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P.H.U. TECHNOMEX Sp. z o.o.
ul. Szparagowa 15
44-141 Gliwice
Poland

has established and applies a quality management system
for the following scope:

**Design and development, production, distribution,
installation and servicing of rehabilitation
and physical therapy devices**

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60084023 0001

An audit was performed. Report No.: 26300170 002

This Certificate is valid until: 12.03.2018

Certification Body

Date 13.03.2013



D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60084021 0001

Report No.: 26300170 002

Manufacturer: P.H.U. TECHNOMEX Sp. z o.o.
ul. Szparagowa 15
44-141 Gliwice
Poland

Products:

- Devices for hydrotherapy
- Devices for hydrotherapy combined with electrotherapy
- Devices for cryotherapy
- Traction units, active

Replaces Approval, Registration No.: DD 60078568 0001

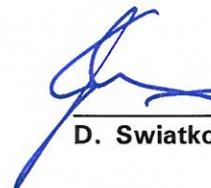
Expiry Date: 2018-03-12

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2013-03-13

Date: 2013-03-13

Notified Body



D. Swiatko



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.