

DECISION

on a quality system and product range covered, based on Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Annex V Section 3.

Decision no.:	VTT-C-5218-01-1143-376-10-P0
Manufacturer:	Valkee Oy Kiilakiventie 1, FI-90250 Oulu Finland
Date of application:	20.11.2009 / Antti Aunio
Activity and product category:	Manufacture and final inspection of light therapy devices.
Decision:	A certificate will be issued for the manufacturer. The certificate covers the following products: <ul style="list-style-type: none"> • Light Therapy Device, Valkee NPT 1000, class IIa • Light Therapy Device, Valkee NPT 1001, class IIa
Justification:	The manufacturer's quality system has been assessed and VTT Expert Services Ltd has found that the quality system and the products meet the requirements of Annex V of Medical Device Directive 93/42/EEC in manufacture and final inspection. The decision is based on report no. NB-1143-A1 The company has signed the undertaking to follow the obligations of Annex V of the Directive.
Certificate related to decision:	VTT-C-5218-01-1143-376-10
Valid until:	This decision is valid until 31 st March 2015 unless the validity of the related certificate is changed.
Date:	Tampere, 31 st March 2010




Kaarle Kylmä


Seppo Lavonen

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.