BIOPTRON®
LIGHT THERAPY SYSTEM By Zepter Group

Device Description
Product Classification Protocol EU

DEDE_All_Product-Classification-Protocol.docx

Directive: 93/42/EEC, Annex IX

Manufacturer Name: BIOPTRON AG
Sihleggstrasse 23
8832 Wollerau
Switzerland

GMDN	Product	Sales Item Code	Class / Rule
35239 Light therapy unit, photo	BIOPTRON MedAll	PAG-960	Class IIa Rule 9
35239 Light therapy unit, photo	BIOPTRON Floor Stand MedAll (Accessory)	PAG-964-FSM	Class I Rule 1
35239 Light therapy unit, photo	BIOPTRON Pro1	PAG-990 / PAG-991	Class IIa Rule 9
35239 Light therapy unit, photo	BIOPTRON Floor Stand Pro1 (Accessory)	PAG-991-FS	Class I Rule 1
35239 Light therapy unit, photo	BIOPTRON 2	PAG-880	Class IIa Rule 9
35239 Light therapy unit, photo	BIOPTRON Floor Stand B2 (Accessory)	PAG-883-Y	Class I Rule 1

The products are not IVD medical devices
The products have no measuring functionality
The products are non-sterile products

Applied Rule: Rule 9
All active therapeutic devices intended to administer or exchange energy are in class IIa. They do not administer or exchange energy to or from the human body in a potentially hazardous way

Applied Rule: Rule 1 (all Floor Stand / Accessories)
All non-invasive devices are in Class I, unless one of the rules set out

Wollerau, November 4th, 2013

Mike Seidenberg
Quality Management Responsible

Niklaus Schulz
General Manager

Explanation for classification according EU directive 93/42/EEC, Annex IX

		Applicable	Class
1	**Non-invasive medical devices**	**Yes**	
Rule 1	All non-invasive devices are in Class I, unless one of the rules set out	Yes	Class I
Rule 2	All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:	No	
Rule 3	Rule 3 – Non-invasive devices that modify biological or chemical composition of blood, body liquids or other liquids intended for infusion into the body	No	
Rule 4	Rule 4 - Non-invasive devices which come into contact with injured skin	No	
2	**Invasive medical devices**	**No**	
Rule 5	Devices invasive with respect to body orifices	-	
Rule 6	Surgically invasive devices intended for transient use (< 60 minutes)	-	
Rule 7	Surgically invasive devices intended for short-term use (>60 minutes, <30 days)	-	
Rule 8	Implantable devices and long-term surgically invasive devices (> 30 days)	-	
3	**Active medical devices**	**Yes**	
Rule 09	Active therapeutic devices intended to administer or exchange energy	Yes	Class IIa
Rule 10	Active devices for diagnosis	No	
Rule 11	Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body	No	
Rule 12	All other active devices	No	
4	**Special Rules**	**No**	
Rule 13	Devices incorporating, as an integral part, a medicinal product or a human blood derivative (See MEDDEV. 2.1/3 for further guidance)	-	
Rule 14	Devices used for contraception or prevention of sexually transmitted diseases	-	
Rule 15	Specific disinfecting, cleaning and rinsing devices	-	
Rule 16	Devices to record X-ray diagnostic images	-	
Rule 17	Devices utilising animal tissues or derivatives	-	
Rule 18	Blood bags	-	

The BIOPTRON medical devices are classified as Class IIa according above explained rules (highest level).

The BIOPTRON floor stands (accessories) are classified as Class I according above explained rules (highest level).