Philips Consumer Lifestyle B.V.
Drachten
The Netherlands

Review of the technical dossier for CE marking of the PulseRelief TENS device (PR3840) (Class IIa), in accordance with the requirements of Annex V+VII of the MDD 93/42/EEC

Report date: November 13, 2014
Report identification: 2174575-TDR18-R1

DEKRA Certification B.V
Arnhem, The Netherlands

On behalf of DEKRA Business Line Medical:

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Client information:

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DEKRA review information:

Report identification	:	2174575-TDR18-R1
Activity date(s)	:	November 14
Content of report	:	Review of the technical dossier for CE marking of the PulseRelief TENS device (PR3840) (Class IIa), in accordance with the requirements of Annex V+VII of the MDD 93/42/EEC *This report includes the review of corrective actions*

TECHNICAL DOSSIER REVIEW REPORT

1 GENERAL ASPECTS

Submitted manufacturer's compliance documents:

- Device description MountainMaple, D000003006, 1.0, 20-8-2014
- Difference between TensRelief and PulseRelief, 25-9-2014

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC

Review description and results:

Philips Consumer Lifestyle B.V. has submitted a Technical Dossier for the PulseRelief TENS device (PR3840). The device is a wireless transcutaneous electrical nerve stimulation (TENS) and electrical muscle stimulation (EMS) device connected to the skin with electrodes pads for pain relief and electrical muscle stimulation. The device includes a control unit, electrodes and mains adapter. It is controlled via a Blue Tooth connected mobile phone device app.

The device is a line extension of the existing approved TENS devices (PR3093 and PR3094). The devices are compared in the table below:

Specification	***TensRelief (current approved device PR3093 and PR3094)***	***PulseRelief (new PR3840)***
Intended use	Chronic mild to moderate musculoskeletal pain	Chronic mild to moderate pain and acute mild to moderate postsurgical pain. EMS can be used for: - Muscle strengthening / rehabilitation / reeducation - Preventing or delaying muscle disuse atrophy - Increasing local blood flow
Modes	TENS	TENS / EMS
Programs fixed	15	20
Programs programmable	5 (PC application required)	None

Specification	***TensRelief (current approved device PR3093 and PR3094)***	***PulseRelief (new PR3840)***
Pulse shape	Symmetric biphase	Symmetric biphase
Max current	60 mA	60 mA
Channels	1 or 2	1

DEKRA Certification B.V. is identified as notified body in the technical dossier.

The PulseRelief TENS device (PR3840) is classified as a class IIa device according to rule 9 of Annex IX of the MDD 93/42/EEC. The following rationale is used for this classification: It is an active therapeutic device intended to administer or exchange energy in a non-hazardous way.
This classification can be accepted by the DEKRA reviewer.

The conformity assessment route followed is Annex V+VII of the MDD 93/42/EEC.

The following critical subcontractors are used for the design and/or manufacture of the device:

- Shenzhen Dongdixin Technology Co., Ltd. (Caretalk)
  No. 3 Building XiliBaimang Xusheng Industrial Estate
  518108 Nanshan Shenzhen
  China
  SDT is used for manufacturing of the device.
- Axelgaard Manufacturing Co.Ltd.
  520 Industrial Way
  Fallbrook, California
  92028
  USA
  Axelgaard is used for manufacturing of the electrodes. Axelgaard is an existing critical subcontractor of Philips Consumer Lifestyle.
- Sogeti Nederland B.V.
  Lange Dreef 17
  4131 NJ Vianen
  The Netherlands
  Sogeti is used for design and development of the mobile phone device app.

More information can be found in the chapter regarding manufacturing information.

Certification structure:
Philips Consumer Lifestyle has an existing CE certificate (86443CE03) with the following scope: Transcutaneous electrical nerve stimulators (TENS) for the treatment of mild to moderate chronic musculoskeletal pain. The addendum of the certificate mentions the following devices:

- Wireless TENS (PR3093)
- Wireless TENS pro with wireless TENS PC application (PR3094)

The certificate is based on the conformity assessment procedure in accordance with Annex V in combination with Annex VII of the MDD 93/42/EEC for class IIa devices. The certificate is valid until 1 July 2016.

Upon approval of the PulseRelief TENS device the scope of CE certificate 86443CE03 shall be updated to: **Transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulation (EMS) for the treatment of mild to moderate chronic musculoskeletal pain and acute mild to moderate postsurgical pain and muscle strengthening**
The addendum of the certificate shall be updated in the following way (changes in **bold**):

- Wireless TENS (PR3093) **TENS**
- Wireless TENS pro with wireless TENS PC application (PR3094) **TENS**
- **PulseRelief TENS (PR3840) TENS and EMS**

See TDR18/Ac01.

Review focus:
Based on the similarities with the existing approved TENS devices the review will focus on the electrical muscle stimulation. The following subjects will be reviewed: risk management, essential requirements, declaration of conformity, performance, safety, EMC, usability, software, clinical evaluation, manufacturing information and labeling.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met.

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2 DEVICE DESCRIPTION

Submitted manufacturer's compliance documents:

- MountainMaple Device description, D000003006, 1.0, 20-8-2014
- Claim list, D000001349, 26-8-2014
- System requirements, D000001330, 1.0, 10-9-2014
- Architectural design MountainMaple, D000002610, 1.1, 10-9-2014
- Boundary conditions MountainMaple, D000002614, 1.2, 24-9-2014
- User requirements MountainMaple, D000002721, 30-7-2014
- User requirements App MountainMaple, D000002728, 30-7-2014

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC

Review description and results:

The device is wireless transcutaneous electrical nerve stimulation (TENS) and electrical muscle stimulation (EMS) device connected to the skin with electrodes pads for pain relief and electrical muscle stimulation. The device includes a control unit, electrodes and mains adapter. It is controlled via a Blue Tooth connected mobile phone device app.

The system is intended to be used by adult consumers experiencing mild to moderate chronic pain or acute post-surgical pain. The system is intended to be used for transcutaneous electrical nerve stimulation (TENS) for the purpose of pain relief. Furthermore, the system is intended to be used for electrical muscle stimulation for the purpose of muscle stimulation. The system is intended for home use.

Device specifications can be found in the table below:

Description	***Specification***
Number of channels	1
Interval between treatment intensity increments	> 300 ms
Pulse shape	Biphase symmetrical
Maximum current output	60 mA at 500-600 Ohm
Current step size	1 mA
Maximum output voltage	60 V

Description	***Specification***
Treatment programs available - Conventional TENS - Burst TENS - Frequency modulated TENS - EMS	20 6 5 4 5
Power consumption	Capable of 8 hours continuous operation

Parameter ranges:

Stimulation type	***Pulse frequency***	***Burst frequency***	***Number of pulses within burst***	***Modulation speed (steps of)***	***Pulse width***	***Preset time***
Conventional TENS	2-100 Hz	NA	NA	NA	60-250 µs	30 min, infinite minutes
Burst TENS		1-3 Hz	5-7	NA		
Frequency modulated TENS		NA	NA	2-3 sec		
EMS	40-65 Hz	NA	NA	1-16 sec	150-350 µs	30 min

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met.

3 RISK MANAGEMENT

Submitted manufacturer's compliance documents:

- Risk management plan MountainMaple, D000002607, 16-9-2014
- User FMEA MountainMaple, D000001312, 26-8-2014
- Safety risk assessment MountainMaple, D000001349, 26-8-2014
- Safety risk management report MountainMaple, D000002608, 16-9-2014
- App user FMEA, D000002724, 26-8-2014
- Safety risk management evaluation report MountainMaple, D000003046, 10-9-2014
- DFMEA, LT5006, version 1.2, 17-9-2014
- PFMEA, LT5006, version 1.2, 17-9-2014

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN ISO 14971:2012, Medical devices - Application of risk management to medical devices

Review description and results:

The manufacturer has submitted risk management documentation based on the international harmonized standard EN ISO 14971:2012.

The Risk Management documentation describes the product, including accessories.

A Risk Management plan for the lifetime of the product is provided. It could be verified that the plan describes:

- Scope; description of the device and life-cycle phases
- Responsibilities and authorities
- Requirements for review
- Criteria for acceptable levels
- Verification activities
    - Implementation
    - Effectiveness
- Activities, collection and review of production and post-production information

The individuals (expertise) that participated in the set up of the Risk Analysis are identified:

- Integral project leader (project management)
- System architect (design risks)
- Safety & compliance (safety risks)
- Product researcher (usability)
- Quality project lead (coordination)
- New product introduction (supplier risks)
- Claims research and clinical studies (claim and substantiation)

The persons of the risk management team can be accepted by the reviewer to cover the applicable subjects for the device under review. However, specifications of competences and expertises could not be found. See TDR18/R01.

The main hazards of the product for the patient and/or user are:

- Misuse can cause burns
- User uses device to stimulate contraindicated places (e.g. chest, neck)

Furthermore, it could be verified that other relevant hazards, like electric shock, biocompatibility hazards of the electrodes, software hazards and usability hazards are included in the risk analysis.

The following aspects for each main hazard have been sufficiently addressed:

- The risk analysis
- The risk evaluation
- The implementation and verification of the risk control measures
- The assessment of the acceptability of any residual risk(s)

No Risk / benefit assessment could be found for the overall risks and individual risks. See TDR18/R02.

The risk management documentation addresses sufficiently the following items:

- Risk analysis for the various components
- Risk analysis for the clinical use
- Risks associated with ergonomic and/or environmental factors
- Risks associated with technical knowledge, education or experience of users
- Risk analysis for the manufacturing process

The manufacturer has provided a statement that device intended use constitutes acceptable risks when weighted against the benefits to the patient and is compatible with a high level of protection of health and safety (MDD, Annex I, ER 1).

The submitted risk management documentation can be accepted by the reviewer. Implementation of risk control measures will also be reviewed in the remainder of this report.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Minor non-conformities:

TDR18/R01 Specifications of competences and expertises of the persons involved in the risk management team could not be found. Functions and responsibilities are not considered information regarding a persons specific expertise.

Response Philips:
Within Philips CL, training records are being stored in our electronic training database. A screenprint from our electronic training database (specified to risk management) is added in TDR18R0.zip, together with training records from 2 team members who were trained before joining Philips CL.

Comments DEKRA Certification:
Sufficient competences and expertise for the risk management team were demonstrated by the submitted documents. This minor nonconformity is closed. See however TDR18/obs01

TDR18/Obs01 Section 3.3 of EN ISO 14971:2012 requires that the members of the risk management team have the appropriate knowledge and experience for their role as member of the risk management team. As stated in the non-conformity functions and responsibilities are not considered competences or experience. It is expected that the risk management file is updated accordingly.

TDR18/R02 No risk / benefit assessment of the overall risks and individual risks can be found according to EN ISO 14971:2012.

Response Philips:
In section 3.5.2 of D000002608 MountainMaple SafetyRiskManagementReport, the following is stated regarding benefit/risk:

4	Discretion as to whether a risk-benefit analysis needs to take place	Risk/benefit assessment is performed in [SRA]. It includes a table on acceptability levels, which only distinguishes acceptable and not acceptable. There are no risks identified in this low-risk device for which benefit/risk applies: there was no risk identified which could not be mitigated /avoided to acceptable levels by e.g. hardware design.

In section 5.1 of D000002608 MountainMaple SafetyRiskManagementReport, states: 'All risks have been sufficiently reduced through control measures during the development process; all residual risks are acceptable. The overall residual risk is accepted and all conditions to start PMS are in place.'.

Comments DEKRA Certification:
The provided response can be accepted. This minor nonconformity is closed. See however TDR18/obs02

TDR18/Obs02 Deviation 4 of Annex ZA of EN ISO14971:2012 requires a risk benefit analysis for each risk identified by the manufacturer independent whether the residual risk has been assessed as acceptable

4 ESSENTIAL PRINCIPALS AND EVIDENCE OF CONFORMITY

Submitted manufacturer's compliance documents:

- Essential requirements checklist, D000003041, 4-8-2014
- Declaration of conformity, draft, 2014/09

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- List of harmonized standards published in the Official Journal – OJ C 149 of 16/05/2014

Review description and results:

List of international (or other) standards

The manufacturer has provided a list of all applicable standards (European or other standards used by manufacturer), including year of reference, which are actually used by the manufacturer. The DEKRA reviewer can accept the list to cover the applicable product standards for the PulseRelief TENS device (PR3840). One minor remark is made regarding versions of standards. See TDR18/R03.

Essential Requirements

The manufacturer has provided a checklist, to show how compliance with the Essential Requirements (following Annex I of the MDD) is addressed.
In the checklist reference is made per Essential Requirement to:

- The Essential Requirements
- Whether the requirement is applicable to the device and if not, a specification why not
- Actual standards used by the manufacturer including version which are used to demonstrate compliance to the Essential Requirements
- The precise identity of the controlled document(s) that offers evidence of conformity

The Essential Requirements checklist provided for PulseRelief TENS device (PR3840) did fulfill the above stated criteria. The DEKRA reviewer concludes that the Essential Requirements checklist is deemed sufficient. One minor remark is made regarding versions of standards. See TDR18/R03.

Declaration of Conformity (draft)

The manufacturer has provided a Declaration of conformity for the submitted products and accessories. The contents of the Declaration of Conformity were reviewed and can be accepted. The submitted Declaration of Conformity contains the name and address of the manufacturer, identification of the notified body, reference to the Medical Device Directive 93/42/EEC, conformity assessment route, classification of the device and time related information.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Minor non-conformities:

TDR18/R03 The applicable standards list / essential requirement checklist do not specify for all standards used the version (year).

Response Philips:
D000003041 MountainMaple MDD Essential Requirements Checklist is updated (attached)

Comments DEKRA Certification:
It was observed that submitted document list for each used standard the publication date. This minor nonconformity is closed.

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5 SUMMARY OF DESIGN VERIFICATION/VALIDATION

Submitted manufacturer's compliance documents:

- Confirmation email of TÜV Rheinland, 16-9-2014
- Design verification strategy MountainMaple, D000001339, 8-7-2014
- Test design MountainMaple, D000001340, 23-9-2014
- Verification report MountainMaple, D000001345, 23-9-2014
- Validation report MountainMaple, D000001311, 17-9-2014
- Usability engineering file MountainMaple, D000002603, 12-9-2014

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN 60601-1:2006 / AC:2010, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2007 / AC:2010, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-6:2010, Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 60601-1-11:2010, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10: medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- EN 62366:2008, Medical devices - Application of usability engineering to medical devices

Review description and results:

The product verification and performance review is based on the product specifications and requirements of Philips Consumer Lifestyle B.V.. Philips Consumer Lifestyle B.V. has provided the system requirements for the PulseRelief TENS device (PR3840).

The purpose of the review is to verify whether all system specifications as described in the product specifications and labeling (product labels and all manuals), including compliance with the individual standard requirements were met.

Overview of tests, including the supported reports and conclusions can be found in the tables below. The DEKRA conclusions can be found in the last column of the tables. A short description of the DEKRA reviews and comments are in the text section below the tables (if needed).

Note: Certain verification and validations are described in other chapters of this report. These are: software, labeling (product labels and all manuals) and clinical validation.

Design assurance (performance)

Test description	***Test samples***	***Test result / Conclusion Philips Consumer Lifestyle B.V.***	***DEKRA comment***
General treatment functions			Accepted
- Number of channels	By design	Pass	
- Increment interval	1	Pass	
- Reset intensity at no connection	2	Pass	
- Manual switch off treatment	2	Pass	
Pulse parameters			Accepted
- Biphase pulse	5	Pass	
- Primary phase charge transfer	1	Pass	
TENS programs (20)	5 samples for each program	All programs are passed	Accepted
Power functions			
- Autonomy time	1	Pass	Accepted
- Charging time	5	Pass	
- Charging cycles	1	Pass	
- Auto-off	5	Pass	
Dimensions	5	Pass	Accepted
System interfaces			Accepted
- Wireless communication	By design	Pass	
- App user interface	2	Pass	
- System data logging	2	Pass	

Test description	***Test samples***	***Test result / Conclusion Philips Consumer Lifestyle B.V.***	***DEKRA comment***
Cleaning - Water cleaning resistant - Ethanol cleaning resistant - Sweat resistant - Crème resistant	 2 2 2 2	Pass	Accepted
Boundary conditions - Operational temperature - Operational humidity	 3 3	Pass	Accepted

From the information submitted it could be verified that all performance tests are passed for the PulseRelief TENS device (PR3840). This is accepted by the reviewer.

Safety of Medical electrical devices

The PulseRelief TENS device (PR3840) of Philips Consumer Lifestyle B.V. has been tested against various safety standards applicable for medical electrical devices. The focus of the safety tests are the subjects covered in the IEC 60601 – series, except software, EMC and Usability aspects which are described below.

These safety tests were out-sourced to accredited (CB) laboratories for these standards. The TÜV Rheinland test laboratories were used for testing against the standard(s):

- EN 60601-1:2006 / AC:2012
- IEC 60601-2-10:2012
- IEC 60601-1-11:2010

The TÜV Rheinland test laboratories conclude that the equipment under test fulfills all relevant requirements of the standard(s).

The formal test reports are under preparation by TÜV Rheinland, however TÜV has confirmed by email (dated 16-9-2014) that all tests are finished and the device fulfills the relevant requirements of the standard. See TDR18/R04.

Electromagnetic compatibility

The PulseRelief TENS device (PR3840) of Philips Consumer Lifestyle B.V. has been tested against the EMC requirements which are described in the following standard(s):

- EN 60601-1-2:2007 / AC:2010
- IEC 60601-2-10:2012

These EMC tests were out-sourced to accredited laboratories (CB) for these standards. The TÜV Rheinland test laboratories were used for testing against these standards.
The focus of the EMC review is on the results of emission and immunity testing, including specific labeling aspects regarding EMC. The TÜV Rheinland test laboratories conclude that the equipment under test fulfills all relevant requirements of the standard(s).

The formal test reports are under preparation by TÜV Rheinland, however TÜV has confirmed by email (dated 16-9-2014) that all tests are finished and the device fulfills the relevant requirements of the standard. See TDR18/R04.

Usability

The device is intended to be used by pain patients in a home situation.

From the usability engineering file it could be verified that the manufacturer has determined the following aspects:

- Frequently used functions
- Identification of hazards and hazardous situations related to usability
- Primary operating functions
- Usability specification
- Usability validation plan
- User interface design and implementation
- Usability verification
- Usability validation

The usability validation shows several test cases which failed, however the provided table indicates that none of them is related to safety which is confirmed by the risk management documentation. Therefore, Philips Consumer Lifestyle concludes that these failed requirements will not cause any risks to the user. In addition, a qualitative post market surveillance user validation test will be set up and executed after market launch.
The failed usability validation tests can be accepted by the reviewer based upon the provided rationale that these issues do not affect the safety of the device and mainly cause user

annoyance. The results of the qualitative post market surveillance user validation test will be reviewed during the next regular audit at Philips Consumer Lifestyle. See TDR18/Ac03.

It could be verified that the accompanying documents include a concise description of the medical device, which includes the operating principle, signification physical characteristics, significant performance characteristics and the intended user profile.

From the submitted information it can be concluded that the usability aspects for PulseRelief TENS device (PR3840) are sufficiently taken into account.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Minor non-conformities:

TDR18/R04 The formal test reports (safety and EMC) are under preparation by TÜV Rheinland, however TÜV has confirmed by email (dated 16-9-2014) that all tests are finished and the device fulfills the relevant requirements of the standard.
TÜV has verified compliance with the following standards:

- IEC 60601-1:2005 / AC:2012
- IEC 60601-1-2:2007 / AC:2010
- IEC 60601-1-11:2010
- IEC 60601-2-10:2012

Response Philips:
Test reports have been received. See attached.

Comments DEKRA Certification:
Philips has submitted the following test reports from the accredited test laboratory TÜV Rheinland:

- IEC60601-1:2005 + Amendment 1:2012 & IEC60601-1-11:2010 & IEC60601-2-10:2012; Ref 17042221001
- IEC60601-1-2:2007; Ref 16062285 001.

The submitted documents could be accepted by the reviewer. This minor nonconformity is closed.

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6 SOFTWARE

Submitted manufacturer's compliance documents:

- MountainMaple software classification for embedded software and software app, MMR0037, rev. A
- Compliance reports device software TRF IEC 62304, D000001348, 24-9-2014
- TRF 62304 SW app, date unknown
- Software analysis report, DDX-LT5006-CE-11-1, version 1.1
- Software requirements specifications, DDX-LT5006-CE-11-2, version 1.0
- Software design specification, DDX-LT5006-CE-11-3, version 1.0
- Software verification and validation, DDX-LT5006-CE-11-4, version 1.0
- Software architecture document app, SAD-PPRAP, version 1.0, 27-6-2014
- FMEA PPRAP basis, 23-4-2014
- FMEA PPRAP details, 27-8-2014
- Risk handling plans, dates unknown
- Traceability matrix app, TM-PPRAP, version 1.3

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN 62304:2006 / AC:2008, Medical device software – Software life-cycle processes

Review description and results:

The software of PulseRelief TENS device (PR3840) of Philips Consumer Lifestyle B.V. consist of embedded and stand-alone software.

Philips Consumer Lifestyle B.V. has used the EN 62304 for the software development life cycle. Philips Consumer Lifestyle B.V. has classified the Software Safety Classification as level A. According to the risk analysis the software can contribute to a hazard, therefore is initially classified as class B. The software related hazards concerns the intensity of the output of the device, as this is controlled by a hardware control measure the software safety classification can be reduced from B to A. This classification can be accepted by the reviewer. It is noticed that the software documentation related to the app classifies the software as level B instead of A. See TDR18/R05.

The embedded software can control the treatment program, treatment time, treatment degree and selecting a different treatment mode.

The software version submitted is not specified. See TDR18/Q01.

The following software documentation was provided:

- Software requirement specification. These could not be found for the app. See TDR18/Q02.
- Software Architecture description. Identifying the modules/functional units of the software and their interfaces.
- Traceability information, showing traceability between requirements (high level, SW requirements and Mitigations) and verification/validation activities.
- Verification and Validation Documentation.
  This included:
  - A Verification / Validation Plan:

  This plan identified / described:
    - What will be tested and what will be excluded
    - The various test levels of the SW life-cycle process with the input and output acceptance criteria (i.e. number of bugs with a certain severity etc.)
    - Regression testing
    - Test environment (hardware and software)
    - Responsibilities
  - System Level Test Reports (including test specification, pass/fail criteria)

  Test reports identified:
    - The SW version tested
    - The test environment used (may refer to ver/val test plan)
    - The tester(s)
    - References to problem reports for any “bug” found.
  - Verification and validation summary.

  Identifying:
    - The concerning software version. Not yet specified, see TDR18/Q01.
    - The test results
    - The unresolved anomalies, including rationales why these anomalies are acceptable.
    - A general conclusion on the acceptability of the software version.
    - The functions approving the summary.
- Unresolved Anomalies: See Verification and Validation Summary above.
  No unresolved anomalies are documented.

Philips Consumer Lifestyle has provided two compliance documents to show that for the embedded software and the stand alone software all requirements of the EN 62304 are fulfilled. Nevertheless, it is noticed that several clauses are not yet passed (for example, the contents of the software development plan). Besides the raised questions and minor non-conformity below an action item is opened to review the compliance of the software lifecycle process with EN 62304 during the next regular audit planned at Philips Consumer Lifestyle. See TDR18/Ac04.

The DEKRA reviewer has reviewed the documentation on the following aspects: risk acceptance criteria, completeness of SW specifications, test plans covering the specifications, verification and validation test are completed and all the acceptance criteria were met. DEKRA cannot yet accept the results.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Minor non-conformities:

TDR18/R05 It is noticed that the software documentation related to the app classifies the software as level B instead of A.

Response Philips:
The software supplier (Sogeti) has been given the assignment to develop the software according to class B. However the classification of the software based on risk assessment is class A.

The software architecture document SAD-PPRAP_SoftwareArchitecture, did not clearly reflect the above. We updated the document (attached).

The software development plan PP-PPRAP_ProjectPlan_PhilipsPainReliefApp states:

> The requirements for software class B according to IEC 62304 are used for developing the product.
> This does not mean that the iOS app is classified as B as such.
> The software risk analysis will reveal the correct software classification and the EVR-PPRAP will report the classification.

The End Verification Report (EVR-PPRAP) states:

> The system risk analysis [HBSRA] did not reveal any iOS software

functionality that contributes to patient hazard or iOS software functionality that is used solely as control measure of a patient hazard without any hardware control measure(s).
Therefore the iOS app software is to be classified as A.

the software TRF: IEC62304ed.2 TRF-PPRAP, section 4.3 states

Class A: No injury or damage to health is possible X
Class B: Non-SERIOUS INJURY is possible N/A
Class C: Death or SERIOUS INJURY is possible N/A

Section 3.4 of D000002608 MountainMaple SafetyRiskManagementReport states:

"It is concluded that both the embedded software of the device and the mobile software app have software classification A."

Comments DEKRA Certification:
The submitted response has been accepted. This minor nonconformity is closed.

Question(s):

TDR18/Q01 Please specify which software versions are submitted for:

a) Embedded software (device firmware)
b) Stand alone software (app)

Response Philips:
App software version for verification test: v0.7
Firmware version of device: v1.7.
This is reflected in updated document D000001345 Mountain Maple Verification Report (section 5.1).

Comments DEKRA Certification:
The submitted response has been accepted. This question is closed.

TDR18/Q02 Please submit the software requirements specifications for the mobile app.

Response Philips:
The software requirement for the mobile app are specified in the document D000002620 MountainMaple Mobile App Requirements (see folder 2.11.2

Detailed Product Specifications)

Comments DEKRA Certification:
It was observed that the indicated document contains the software requirements of the Mobile App. This question is closed.

7 CLINICAL EVALUATION

Submitted manufacturer's compliance documents:

- Clinical evaluation report, D000001313, 10-9-2014

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice
- EN ISO 14971:2012, Medical devices – Application of risk management to medical devices
- MEDDEV 2.7/1 rev. 3, December 2009, Clinical evaluation: Guide for manufacturers and notified bodies
- MEDDEV 2.12/2 rev. 2, January 2012, Post Market Clinical Follow-up studies

Review description and results:

The manufacturer supplied the documentation as required by the MEDDEV 2.7.1/ rev 3.0.

The following claims are made by the manufacturer:

- Transcutaneous electrical nerve stimulation for the treatment of mild to moderate chronic pain, acute post surgical or post-traumatic pain
- Electrical muscle stimulation for muscle strengthening and rehabilitation, preventing and delaying muscle disuse atrophy and increasing local blood circulation

Focus will be on the underlined claims as they are different compared to the previous approved TENS device.

As both TENS and EMS are well known medical treatments the literature route is used to demonstrate clinical safety and performance.

The search strategy and selection criteria are documented in the clinical evaluation report.

For each claim the selected articles are discussed. Philips Consumer Lifestyle draws the following conclusions:

- Based on the clinical evidence (systematic review on TENS for different conditions) that has been presented in the previous sections, we conclude that TENS can help to relieve mild to moderate chronic pain and mild to moderate acute post-surgical pain.

Regarding safety: the contra-indications to TENS are few and serious adverse events are rare. This is confirmed by two other systematic reviews and a search in the MAUDE database.

- EMS: Although the evidence from literature is limited by the small numbers of subjects and lack of adequate controls, electrically stimulated muscle contractions have proved helpful for muscle strengthening and rehabilitation as well as for the prevention or delay of muscle disuse atrophy in the context of orthopedic conditions.
  Regarding safety it is concluded that very few adverse events result from the clinical application of electrical currents. This is confirmed by a search in the MAUDE database.

The appendix of the clinical evaluation consists of tables in which the parameters used in each study are compared with the PulseRelief device. It could be verified that the parameter range of the PulseRelief device is equivalent whit the device parameters discussed in the clinical literature.

The DEKRA reviewer concludes the following with regard to the submitted clinical evaluation: The risks identified in the risk analysis were correct and complete and sufficiently addressed. Overview of data was complete and up-to-date, presenting both favourable and unfavourable data. The presented data were relevant to demonstrate clinical safety and performance of the device. Clinical safety and performance of the device is demonstrated. The claims were substantiated. The information provided in the instructions for use can be accepted.
The conclusion regarding the risk/benefit ratio can be accepted.

The DEKRA reviewer can accept the clinical evaluation.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met.

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8 MANUFACTURING INFORMATION

Submitted manufacturer's compliance documents:

- Device description, D000003006, 1.0, 20-8-2014
- EN ISO 13485:2012 certificate SDT, SX 60082813 0001, 12-4-2013
- ISO 9001:2008 certificate Sogeti, 2074314, 1-7-2013
- ISO 13485:2003 certificate Axelgaard, FM 40363, 3-11-2012

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC

Review description and results:

The manufacturer has identified the following critical (sub-) contractors that have a role in the manufacture of the device:

Component	***Description activities***	***Subcontractor***	***Certification***
TENS / EMS device	Production	Shenzhen Dongdixin Technology Co. Ltd.	EN ISO 13485:2012
Electrodes	Production	Axelgaard Manufacturing Co. Ltd.	ISO 13485:2003
Software app	Design and development	Sogeti Nederland B.V.	ISO 9001:2008

Axelgaard Manufacturing is a known critical subcontractor of Philips Consumer Lifestyle.

The following table indicates the status of the certificates of the critical subcontractors:

Subcontractor	***Certificate***	***Certificate identification***	***Scope***	***Valid until***	***Issued by***
SDT	EN ISO 13485:2012	SX 60082813 0001	Design and development, manufacture and distribution of medical devices	21-6-2016	TÜV Rheinland
Axelgaard Manufacturing	ISO 13485:203	FM 40363	Design and development, manufacture and distribution of hydrogel and non-invasive electrodes	3-12-2015	BSI

Subcontractor	*Certificate*	*Certificate identification*	*Scope*	*Valid until*	*Issued by*
Sogeti Nederland	ISO 9001:2008	2074314	Het verlenen van diensten dmv de volgende servicelines: Consultancy, project-, programma- en servicemanagement, implementatie, hosing en beheer van standaard software, analyse en ontwerp van maatwerk applicatie embedded software, infrastructuren, engineering van maatwerk applicatie/embedded software, infrastructuren, beheer van maatwerk applicatie/embedded software, infrastructuren	1-7-2016	DEKRA Certification

The following critical subcontractor shall be indentified on the Certification Notice (changes are indicated in **bold**):

Company name / address	**Type of service to Manufacturer**	**QS standard and name certifier**	**Certificate number and expiry date**
Shenzhen Dongdixin Technology Co. Ltd. No. 3 Building XiliBaimang Xusheng Industrial Estate, 518108 Nanshan, Shenzhen, China	**Production of PulseRelief TENS device PR3840**	**EN ISO 13485:2012 TÜV Rheinland**	**SX 60082813 0001 21-6-2016**

Company name / address	Type of service to Manufacturer	QS standard and name certifier	Certificate number and expiry date
Axelgaard Manufacturing Co., Ltd. 520 Industrial Way Fallbrook California 92028 USA	**Production and packaging of electrodes for the TENS / EMS device**	ISO 13485:2003, BSI	FM 40363, 03-12-2015
Sogeti Nederland BV Divisies Application New Technology, Application life cycle management, consulting services, infrastructure security & high tech services en software control Lange Dreef 17 4131 NJ Vianen The Netherlands	**Design and development mobile phone device app**	**ISO 9001:2008**	**2074314 DEKRA Certification**

See TDR18/Ac02.

Based on the existing QMS certificates of the new critical subcontractors it is not deemed necessary to conduct additional subcontractor audits before approval of the PulseRelief TENS device.

The manufacturer has provided an overview of the production process in a flow chart format in which all important process steps, the quality inspections, tests and the subcontractors are identified.
Clear references have been made to the DMR and relevant procedures or work instructions.

The DEKRA reviewer can accept the production information provided by the manufacturer.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met.

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9 LABELING

Submitted manufacturer's compliance documents:

- A-box label PR3840 DACH 20140917
- A-box label PR3840 GB 20140917
- Pallet label PR3840 DACH 20140917
- Pallet label PR3840 GB 20140917
- PulseRelief label, D000001319, 7-4-2014
- PulseRelief label, D000001319, 2-4-2014
- Quick start guide, D000003043, date unknown
- Directions for use, D000003042, 19-9-2014
- PR3840 leaflet, version 1.0.1, 16-9-2014

Directive, standards and guidance to which the Notified Body verifies compliance:

- MDD 93/42/EEC
- EN 980:2008, Symbols for use in the labeling of medical devices
- EN 1041:2008, Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2012, Medical devices – Symbols to be used with medical labels, labeling and information to be supplied – Part 1: General requirements
- EN 60601-1:2006 / AC:2010, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2007 / AC:2010, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-10: medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

Review description and results:

Copy of all labeling

The manufacturer has provided copies of the different labels (device label, package label and pallet label), including its locations on the product and/or package.
The submitted labels contain the name and address of the manufacturer, the CE mark with identification of the notified body, year of manufacture and relevant warnings and precautions.

The labels used show full compliance to the labeling requirements in the Essential Requirements of the MDD, the requirements described in EN-980, EN 1041 and product standards specific requirements on labels.

Copy of Instructions for Use

The manufacturer has provided a copy of all the manuals and/or inserts which are provided to the users, patients and technical service personnel. The information in the instructions for use includes instructions regarding service and installation.
The instructions for use contain the name and address of the manufacturer and the latest revision of the instruction for use. For installation of the app the instructions for use refers to the quick start guide. The quick start guide contains the required hardware and software requirements for correct functioning of the app.
The IFU shows no full compliance to the requirements for Instructions for use in the Essential Requirements of the MDD, the requirements described in EN-1041 and product standards specific requirements on IFU's. The following remarks are made:

- The CE mark with identification of the notified body cannot be found on the instructions for use and the quick start guide.
- The following required information cannot be found in the quick start guide: name and address of the manufacuturer, latest revision of the quick start guide and the concerned software version of the app.

See TDR18/Q03.

The warnings referenced in the instruction for use are sufficiently addressed in the risk management file and vice versa.

Marketing brochures (when available) and applicable website addresses

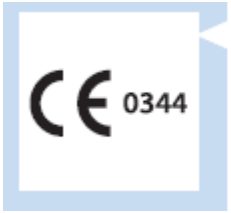
The manufacturer has provided a copy of all the marketing brochures and website addresses. The claims, intended use and product information are consistent, with the product specifications as described in the instruction for use.

The requirements as mentioned in the relevant Annex of the MDD and the international harmonized standard(s) have been met, with exception of the documented findings below:

Question(s):
TDR18/Q03

a) Why is the CE mark with identification of the notified body not included on the instructions for use and quick start guide?

Response Philips:
CE0344 is mentioned in the IFU on page 48:



- This symbol means: Conforms to EC Directives. CE stands for 'Conformité Européenne'. 0344 is the number of the notified body.

The QSG refers to the IFU (by means of symbol ISO 7010-M002).

Comments DEKRA Certification:
The submitted response has been accepted. This part of the question is closed.

b) Why is the name and address of the manufacturer and the latest revision not included on the quick start guide?

Response Philips:
The QSG refers to the IFU (by means of symbol ISO 7010-M002), where the manufacturers address is mentioned on page 1.

The revision number of the QSG is in the last digit of 12NC code (4222.100.3355.1). See page 1.

Comments DEKRA Certification:
The submitted response has been accepted. This part of the question is closed.

c) How is it ensured that the user downloads the latest / correct software version of the app?

Response Philips:
Users who installed the app get automatic notification in iOS when an updated version is available.

The mobile app is classified as Class A according IEC62304, meaning no

injury or damage to health is possible due to failing of software. As the app is classified as class A, there is no need for the user to have the latest version from safety point of view.

Comments DEKRA Certification:
The submitted response has been accepted. This part of the question is closed.

10 CONCLUSION OF THIS REPORT

The Notified Body has accepted the technical dossier for the PulseRelief TENS device (PR3840) for review. The PulseRelief TENS device (PR3840) has been classified as a Class IIa device. A conformity route according to Annex V+VII of the Council Directive 93/42/EEC is followed.

The initial review of the technical dossier resulted in 5 minor non-conformities, 0 major non-conformities, and a total of 3 questions.

After review of the corrective actions the 3 questions and 5 minor non-conformities are closed and 2 observations are added.

Table: status review findings.

Review findings that are addressed satisfactorily:	Review findings that need to be addressed before the next DEKRA Notified Body audit:	Review findings that need to be addressed before CE-certification:
TDR18/R01-TDR18/R05 TDR18/Q01-TDR18/Q03	-	-

Based on the results of this review, it is concluded that the technical dossier for PulseRelief TENS device (PR3840) of manufacturer Philips Consumer Lifestyle B.V. fulfills the obligations imposed by Annex V+VII of the Medical Device Directive 93/42/EEC. CE-approval of PulseRelief TENS device (PR3840) is therefore recommended to DEKRA Certification Business Line Medical's Certification Management Board.

Action(s):

TDR18/Ac01 **DEKRA:** Upon approval of the PulseRelief TENS device the scope of CE certificate 86443CE03 shall be updated to: **Transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulation (EMS) for the treatment of mild to moderate chronic musculoskeletal pain and acute mild to moderate postsurgical pain and muscle strengthening** The addendum of the certificate shall be updated in the following way (changes in **bold**):

- Wireless TENS (PR3093) **TENS**
- Wireless TENS pro with wireless TENS PC application (PR3094) **TENS**
- **PulseRelief TENS (PR3840) TENS and EMS**

TDR18/Ac02 **DEKRA:** The following critical subcontractor shall be indentified on the Certification Notice (changes are indicated in **bold**):

Company name / address	**Type of service to Manufacturer**	**QS standard and name certifier**	**Certificate number and expiry date**
Shenzhen Dongdixin Technology Co. Ltd. No. 3 Building XiliBaimang Xusheng Industrial Estate, 518108 Nanshan, Shenzhen, China	**Production of PulseRelief TENS device PR3840**	**EN ISO 13485:2012 TÜV Rheinland**	**SX 60082813 0001 21-6-2016**
Axelgaard Manufacturing Co., Ltd. 520 Industrial Way Fallbrook California 92028 USA	**Production and packaging of electrodes for the TENS / EMS device**	ISO 13485:2003, BSI	FM 40363, 03-12-2015
Sogeti Nederland BV Divisies Application New Technology, Application life cycle management, consulting services, infrastructure security & high tech services en software control Lange Dreef 17 4131 NJ Vianen The Netherlands	**Design and development mobile phone device app**	**ISO 9001:2008**	**2074314 DEKRA Certification**

TDR18/Ac03 **DEKRA:** The usability validation shows several test cases which failed, however the provided table indicates that none of them is related to safety which is confirmed by the risk management documentation. Therefore, Philips Consumer Lifestyle concludes that these failed requirements will not cause any risks to the user. In addition, a qualitative post market surveillance user validation test will be set up and executed after market launch. The results of the qualitative post market surveillance user validation test will be reviewed during the next regular audit at Philips Consumer Lifestyle.

TDR18/Ac04 **DEKRA:** Philips Consumer Lifestyle has provided two compliance documents to show that for the embedded software and the stand alone software all requirements of the EN 62304 are fulfilled. Nevertheless, it is noticed that several clauses are not yet passed (for example, the contents of the software development plan). DEKRA will review the compliance of the software lifecycle process with EN 62304 during the next regular audit planned at Philips Consumer Lifestyle.

*** END OF REPORT ***

APPENDIX A: DEFINITIONS

The Notified Body review has been carried out in accordance with the relevant requirements of the Conformity Assessment Procedure of the applicable EC-Directive. DEKRA Notified Body distinguishes the following review findings: minor non-conformities, questions and major non-conformities.

Definitions:

Minor non-conformity (R):
A requirement of the applicable EC-Directive has not been fully met. The finding is:
(a) non-systematic; and/or
(b) an isolated occurrence; and/or
(c) not likely to result in the failure of the product performance and/or patient safety.

Major non-conformity (NC):
A requirement of the applicable EC-Directive has not been met. The finding is:
(a) a systematic deviation of the applicable Council Directive; and/or
(b) a failure/deviation that might compromise the performance of the product and/or safety of the patient.

Question:
The reviewed information is not sufficient for the Notified Body to make a statement concerning the status of the finding. Additional information (clarification) from the manufacturer is required. A question has in principle the same status as a major non-conformity and therefore may delay CE-certification.

Observation:
An opportunity for improvement not directly related to a specific requirement of the standard, regulation, quality system and/or MDD/IVDD/AIMDD. Follow up is voluntary and will not further be reviewed by DEKRA.

Corrective actions initial / renewal certification:
The major non-conformity should be corrected and objective evidence of corrective actions taken shall be submitted to the reviewer within 90 days, unless other arrangements have been made and approved.

In the case corrective actions have not been received from the manufacturer within half a year, the review will be stopped and no certification activities will be performed.

Unless stated differently minor non-conformities do hold up certification decisions. Implementation effectiveness of manufacturer's corrective actions will be assessed at the next scheduled audit when appropriate.

Administrative actions:

Assessments of results of corrective action review will be reported.

Version control:

This report is generated through a controlled template, version 1.0.