EC Type-Examination Certificate

521732/1

Date of Issue: **24 October 2014** **Expiry date:** **24 October 2019**

This is to certify that BTTG Testing & Certification Ltd, specified as a "notified body" under the terms of the Personal Protective Equipment Regulations 2002, did undertake the relevant type approval procedures for the equipment identified below which was found to be in compliance with the relevant provisions of EC Directive 89/686/EEC, or as amended, subject to any conditions in the schedule attached hereto.

Manufacturer:	**StemRad Ltd**
Address:	**4 Berkovich Street** **Museum Tower, 18th Floor** **Tel Aviv, 64238** **Israel**
Product Description:	**Protective devices against exposure to high-energy gamma radiation**
Product Code:	**StemRad 360 Gamma**
Technical File reference:	**CE TECHNICAL FILE rev B**
Harmonised Standard(s):	**EN ISO 13688:2013**
Technical Specification:	**CE TECHNICAL FILE rev A**

This certificate relates specifically to the PPE items described and depicted in the manufacturer's Technical File, copies of which are held by the manufacturer and BTTG, and not to any other items.

The attached schedule of approval forms part of this certificate. This certificate remains valid unless cancelled or revoked, provided the conditions in the attached schedule are complied with and the equipment remains satisfactory in service.

Certificate Authorised by: ..... T M Brett
Certification Officer

and: ..... C A Butcher
Certification Manager

Notified Body for PPE Testing & Certification I.D. No. 0338

Issued by BTTG Testing & Certification Ltd., Notified Body Identification No. 0338.

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Schedule of Approval

Certificate No: 521732/1 **Date of Issue: 24 October 2014** **Expiry date: 24 October 2019**

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StemRad Ltd **CE TECHNICAL FILE rev B**

CONDITIONS OF CERTIFICATION

Description of product

Protective devices against exposure to high energy gamma radiation consisting of:

StemRad 360 Gamma

Available in the following materials:

Outer Shell/Inner Lining:	Tecashield® - KR610 (Arashield™); 100% Para-aramid with high solid polymer coating (545 $g.m^{-2}$) (Black/Grey)
Core Pouch:	420D woven Nylon with PU back coating, EDPM profiles and hard pockets
Core:	Stainless Steel, Teflon sheet and Lead composite

Manufacturer's Technical Specification

The manufacturer's Technical Specification for the end use of Protective devices against exposure to high energy gamma radiation was based on testing of the product's attenuation behaviour when exposed to a Cs-137 highly penetrating source, to simulate gamma radiation exposure from a fallout source. The product is intended to protect against death from the Hematopoietic presentation of Acute Radiation Syndrome.

Product design is based upon user morphology requirements (location of strategic concentrations of hematopoietic stem cells), and user ergonomic requirements (encountered by first responders whom remain in disaster zones for extended periods, and by users evacuating from disaster zones), and has considered thermal hazards posed by potential working environments.

The suitability of this specification was checked with respect to the Basic Health and Safety Requirements of EC Directive 89/686/EEC, and was found to address the requirements for this end use.

Limitations of Use

- Usage, maintenance and storage as per manufacturer's instructions.
- It is the end users responsibility to assess the risks of the working environment, taking into consideration potential total dose, type of radiation, age of wearer, general state of health of wearer and time interval over which dose is received and to determine the degree of medical care required after departure from the working environment.
- The product is intended to protect a strategic concentration of Hematopoietic Stem Cells (HSCs) from change, damage or death (allowing for proliferation and self-renewal of blood cellular components when coupled with supportive or intensive medical care) when a wearer is exposed to high energy ionizing gamma radiation, for whole-body acute doses of less than 1000rad.

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Limitations of Use (continued)

- The product is not suitable for protection against Central Nervous System and Gastrointestinal presentations of Acute Radiation Syndrome.
- The product is not suitable for protection against other Acute (high dose) effects such as Moist Desquamation (skin blistering), Dry Desquamation (skin peeling), Epilation (hair loss), Sterility, Erythema (skin reddening), and Cataracts.
- The product is not suitable for protection against Chronic (low dose) effects such as In-Utero (effects on embryo/foetus), Somatic (Carcinogenic effect), and Genetic.
- The product does not offer protection from the thermal effects which may be encountered in a firefighting environment.
- The product does not offer protection from chemical or biological hazards which may be encountered in the working environment during its use.
- The product features an adjustable pocket attached by way of hook and loop fasteners designed to hold a radiation monitor and alarm. This EC Type-Examination Certificate applies only to the StemRad 360 Gamma product. Any radiation monitor and alarm used must be separately examined and certified.
- The product features an internal pocket designed to hold an acute radiation monitor / dosimeter card. This EC Type-Examination Certificate applies only to the StemRad 360 Gamma product, the performance of this card was not considered.

Observations

- The primary outer and lining material has been tested to Heat resistance at 180°C (ISO 17493) and Flame spread (ISO 15025) in accordance with clauses 6.1 and 6.5 of EN 469:2005/A1:2006+AC:2006. This material was found to experience no ignition, melting or shrinkage due to the heat exposure, and no flaming, hole formation, melting, flaming/molten debris, afterflame greater than 2s in duration, after glow greater than 2s in duration when exposed to the flame.
- The product features 3M Scotchlite 8935 garment trim, which has been tested to NFPA 1971 Standard on Protective Ensembles for Structural Fire Fighting and Proximity Fire Fighting, NFPA 1977 Standard on protective Clothing and Equipment for Wildland Fire Fighting and NFPA 1951 Standard on Protective Ensembles for Technical Rescue Incidents and was found to comply with the necessary clauses.
- The product was assessed to Clause 6.13 and Annex D of EN 469:2005/A1:2006+AC:2006 when worn with representative examples of Firefighters' Clothing (consisting of a Jacket and Trouser), Gloves, Fire Hood, Boots and a Self Contained Breathing Apparatus (SCBA, single canister). The product was worn over the Firefighters' Jacket, and beneath the SCBA. The product was found to be satisfactory with respect to all required movements, however the test subject suffered some discomfort in deep breathing when attempting to retrieve a small object from the floor. It should also be noted, that the wearing of the device externally may obscure visibility components of the underlying PPE. An experienced wearer of this type of protective equipment would be expected to be accustomed to the restrictions imposed by the ensemble. The end user must decide on the basis of a risk assessment whether the use of this product is acceptable.

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StemRad Ltd **CE TECHNICAL FILE rev B**

DOCUMENTATION SUBMITTED (Technical File – CE TECHNICAL FILE rev A):

Approval Documents

- Fabric test report No. 30/04285/2
- Ergonomic Assessment test report No. 521732/B/CS
- Innocuousness test report Nos. 2014EP1384
- Innocuousness information - Oeko-Tex Test-No. 06.MA.50313
- Radiation penetration testing on human phantom models detailed in StemRad whitepaper (May 2014)

Product Documentation

- Product description
- Drawings
- Fabric description and test data
- Supplier's Innocuousness statement for fabric
- Component list
- Size chart
- Quality information for manufacturing site
- Labelling
- User Information
- Statement of end use

Terms and Conditions associated with the issue of this EC Type-Examination Certificate

1. This certificate is issued subject to BTTG's standard terms of business.
2. Production is limited to the site(s) listed in the manufacturer's Technical File, copies of which are held by the manufacturer and BTTG, and not to any other production site(s).
3. Any change to the product or quality manual / quality plan shall be immediately notified to BTTG.
4. This certificate is issued in the English language only. It is the responsibility of the Manufacturer / Authorised Representative to obtain and supply language versions acceptable to the country where the product is to be sold.
5. This certificate remains the property of BTTG and will be withdrawn if any of the conditions attached to its issue are not complied with.
6. This certificate does not authorise the use of the Mark of Conformity (the 'CE mark'), which may only be affixed to the above type approved equipment and a Manufacturer's Declaration of Conformity issued when Article 11(A or B) of the Directive is fully complied with and controlled by a written agreement with a notified body.

END OF CERTIFICATE