Statement of Conformity

Name of Manufacturer	:	SIVA Inotec Ltd.
Address	:	N-6, Verna Industries Area, Phase IV, Verna, Goa-403722, India
Product	:	Tourniquet
Model(s)	:	Tourni-S
Class	:	Class I
Classification and Justification	:	As per annexure IX of MDD 93/42/EEC, as amended by 2007/47/EC section 1.1 Rule 1, it's a Class I Medical Device. All non-invasive devices are in Class I.
Technical File Reference	:	SIVA/TCF/001 Rev. No. 00, Issue No :00, Dated Aug 07, 2020

This is to certify that the manufacturer's technical documentation & intended use* according to MDD 93/42/EEC has been reviewed and the information therein found as per requirements of Class I Medical Device Directive 93/42/EEC as amended by 2007/47/EC. Any significant change(s) in the design or construction of the product, not agreed upon us, this declaration shall lose its validity.

**It is a single use disposable tourniquet, a device which applies pressure to a limb in order to limit flow of blood.*

The client may affix CE marking under their own responsibility & liability after completion of compliance with all relevant EC Directives.

The technical report & documentation at the applicant's disposal

Conditions of issue:

This certificate refers to the information examined and read with the manufacturer's declaration of conformity. Any modifications made subsequent to the examination of the documentation, unless approved by URS will nullify this certification.

This certificate relates only to the medical device mentioned above as described in the Technical file on the date shown.

Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacturing & quality control of the product or its nominated representative, in accordance with the EU Directive 85/374/EEC.

Certificate Number	TCF No.	Date of Issue	Validity
COC/IN/062	SIVA/TCF/001	27/10/2020	26/05/2024

Reviewed By:

Approved By

CE The CE Marking may be used when all the relevant & effective EU Directives are complied with CE