EU DECLARATION OF CONFORMITY No 2017/85

1. **Knee Brace X-Frame:** Class II PPE Motorcyclists Impact Protector. (This model is described in the manufacturer's technical file number 85, on file at the Notifying Body.)

2. Manufacturer or authorised representative in the Community:
Leatt® Corporation

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
Leatt Corporation.

4. Object of the declaration

Product Type	Standard Number & Level	Product Reference Name / Code	EU Type Examination Certificate No.
Motorcyclists Knee Protector	EN 1621-1:2012 K Type A Level 1	Knee Brace X-Frame 50180101XX	Intertek LEC FI00370098
			

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: PPE Regulation (EU) 2016 / 425

6. Where applicable, the notified body ITS Testing Services (UK) Limited, Centre Court, Meridian Business Park, Leicester, LE19 1WD, United Kingdom, Notified body No. 0362 performed the EU type-examination (Module B) and issued the EU type-examination certificates detailed in point 4 of this declaration.

Signed for and on behalf of Leatt Corporation at Cape Town, South Africa on 20th March 2019.

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MSD Samara - Pr. Eng.

Certification & Quality

Our Ref: CA014741

11 March 2015

Dear Mr Scott Macfarlane,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- Leatt Corporation**.
Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

Class I Devices:

Orthoses (Lower And Upper Limb/Spinal/Abdominal/Neck/Head)
Orthopaedic Casting/Support Products And Accessories
Knee orthosis

Custom Made Devices:

None

Products Covered By Article 12:

None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.