

DECLARATION OF CONFORMITY

Manufacturer: Tekscan Inc.
307 West First Street
South Boston, MA 02127
USA

Authorized European Representative: Winckels Medical Devices Expertise B.V.
Bergerweg 18
6085 AT Horn
The Netherlands, Europe

Product Name: *T-Scan®*
Product Description Pressure Measurement System, Novus Based

Description of Intended Use: The T-Scan Pressure Measurement System is a device used to sense and measure the Occlusal contact force between human teeth.

Classification: Class I, Rule 12, per MDD 93/42/EEC Annex IX

We herewith declare the products mentioned above meet the provisions of the Council Directives 93/42/EEC for medical devices and 2011/65/EU on the restriction of use of certain hazardous substances in electrical and electronic equipment, RoHS Directive. The declaration is issued under the sole responsibility of the manufacturer. All supporting documentation is retained under the premises of the manufacturer.

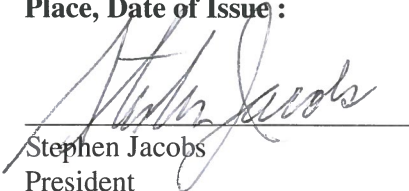
Standards Applied:

A list of Harmonized Standards for which documented evidence for compliance can be provided are included in the Technical Files.

Certificates : ISO 9001:2008 Certificate No. US-2329d-01
ISO 13485:2003 Certificate No. 9172-4-01

Start of CE Marking : All lot/Serial Numbers

Place, Date of Issue : Boston, MA, USA, July 5th, 2017



Stephen Jacobs
President
Tekscan Inc.

Date: 7/12/17



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INFORMATION LETTER

We, Tekscan, Inc., with a registered office at 333 Providence Highway, Norwood, MA, USA, legal manufacturer of the T-Scan Novus and T-Scan Novus Core technology, bring the following information to the attention of all concerned.

T-Scan Novus is Class 1 CE marked medical device which is confirmed by the EU Declaration of Conformity with the requirements of Medical Device Regulation (EU) 2017/745.

In accordance with the Regulation (EU) 2017/745 of the European parliament and of the Council of April 5 2017 (further "Regulation"), Article 52, paragraph 7, manufacturers of class 1 devices, other than custom-made or investigational devices, shall declare conformity of their products by issuing the EU declaration of conformity after drawing up the technical documentation set out in Annexes II and III of the Regulation. The technical File contains or references product-specific documentation, applicable standards, work instructions, specifications, reports, etc., required for design conformity assessment relating to CE Marking of the Pressure Measurement Systems – Novus (DH1) Handle Based. Tekscan Inc. maintains a Quality Management System in accordance with ISO 13485:2016. This Technical File has been assembled to demonstrate conformity to the Medical Devices Regulation (EU) 2017/745.

The EU declaration confirms, the manufacturer shall assume responsibility for compliance with the requirements of the Regulation and all other Union legislation applicable to the device.

Devices considered to be in conformity with the requirements of the regulation shall bear the CE marking of the conformity.

Therefore, we confirm that the CE certificate is not required for T-Scan Novus system and the document confirming the quality, safety, and efficacy of the product is the EU Declaration of Conformity.

Quality Management System Certificate:

ISO13485:2016 Certificate # 9172-8

Standards Applied:

A list of Harmonized Standards for which documented evidence for compliance can be provided and are included in the Technical files.

Conformity Declaration, per MDR (EU745 Annex IV) 2017/745 Annex IV

Authorized Signatory:

Shawn J. Wallace

6-20-2023

Date

The Commonwealth of Massachusetts

On this 20 day of JUNE, 2023
before me, the undersigned notary public, Shawn Wallace
personally appeared, proved to me through
satisfactory evidence of identification, which were
MA Drivers license, to be the person whose name is
signed on the preceding or attached document, and acknowledged
to me that he/she signed it voluntarily for its stated purpose.



Casey Argyrou
CASEY ARGYROU, Notary Public
My Commission Expires October 24, 2025

