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EN 12830 Declaration of Conformance

Declaration of Conformity to European Council Directives

Signatrol Ltd hereby declare that the following temperature recorder products:

Models

- TempMate S1
- SL52T
- SL151T
- SL7000 Series (All Variants)
- SpYdaq
- Cadmus

Manufactured by;

Signatrol Ltd.
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GL20 8SJ
UK

Have been tested and found to comply with the essential requirements of the following European Standard:

- Temperature Recorders EN 12830:2018

Provided that the product has not been modified in any way.

The tests that verified that all models listed above conform to these standards were performed by:

Signed. Martin Westover   Date: 21st December 2020
            Operations Director

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EN 12830 Cold Chain Monitoring

1. Introduction

This document discusses the various clauses in the standard and how compliance is achieved using Signatrol data loggers used only with bespoke software written and distributed by Signatrol Ltd.

2. The Standard

EN-12830:2018 is a Pan-European standard whose full title is: 'Temperature recorders for the transport, storage and distribution of temperature sensitive goods-Tests performance, suitability.

3. Scope

The standard applies to stand alone data loggers and chart recorders with integral sensors or probes connected by wires or radio

4. Applicable Products

SL52T, SL151T, SL7000 series, spYdaq, Cadmus, TempMate S1

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4. Requirements of the Standard

Clause	Requirement	Met
5.1	The means of temperature must be independent of any temperature measurement which us used to control the refrigeration system	All are independent self powered loggers either stand alone or part of a system
5.2	The temperature recorder shall be able to measure in the measuring range that is defined by the manufacturer The measurement range of the sensors must be <-30°C >15°C with minimum span of 50°C	All our loggers for transportation and storage exceed this requirement
5.3.1	The software shall prevent and/or at least detect both intended and not intended manipulation of the relevant data. This is true for all relevant data as long as they are managed by the measurement system, including during storage and transmission.	Time and dates are recorded and form part of the record along with all configuration details. Access to data and configuration is controlled by password so that only authorised users have access. spYdaq uses a Administrator/User hierarchy all password protected. All data are stored in a secure database format that cannot be altered by ordinary means. The raw data for Tempmate data loggers is stored within the device and not accessible.
5.3.3	The software shall be able to present the relevant data in a way that is directly readable by persons or authorities in an easy way.	Data is presented in a graphical way (TempIT-LITE & TempIT-PRO) and in a tabular format (TempIT-PRO). Tempmate data loggers produce PDF reports with both graphical and tabular data.
5.3.4	The software shall have a possibility to make sure the user can access the relevant data any time, provided he/she has the rights to do so	The data are viewed in the native TempIT format within the software. This can be printed or saved in PDF format. Tempmate data loggers produce a PDF file.
5.3.6	The software shall have a possibility to ensure that the data are inviolate.	Access to data and configuration is controlled by password so that only authorised users have access. spYdaq uses a Administrator/User hierarchy all password protected. All data are stored in a secure database format that cannot be altered by ordinary means. The raw data for Tempmate data loggers is stored within the device and not accessible.

5.3.7	The software shall make sure that critical parts of the software can't be accessed without user verification. This means it has to have a user management system with user names and passwords to identify the users, and options to declare user rights to define various user roles (e.g. administrator vs. regular user).	Administrator privileges are password protected. User access is not restricted.
5.5.1	At least the temperature and the time shall be recorded. The record shall also indicate the date and the time zone e.g. GMT or UTC. Other information as the place of measurement (e.g. return air, back door) could be also recorded, however it shall not impact the temperature data.	All readings are time and date stamped. Time zone is determined by the computer operating system. TempIT software provides a user manifest that can be used to record the temperature data logger location.
5.5.2	It shall be possible to identify and retrieve the recorded data. It shall be possible to read those data, intended for archiving for a period of at least a year. The recorder shall allow the user to keep the data for at least one year. After one year the responsibility for the recorded values should be managed between the contracting parties within the cold chain for the different goods after the transfer in regards to relevant regulations and quality requirements including enlarged storage periods i.e. pharmaceutical products, EU food regulations and others. The manufacturer of the device shall define instructions in its documentation for operation and maintenance taking in account, i.e. life time of batteries, storage periods and operational limitations of the device.	For TempMate data loggers, the data is held permanently on the device. The PDF file should be back up once downloaded. TempMate products do not have replaceable batteries and no user maintenance is required. TempIT stores the data on the hard disk of the computer. Procedures should be put in place to the backup this data. SL52T, SL151T have no user replaceable parts and only require annual calibration. SpYdaq and Cadmus transmitters provide battery expiration warnings.
5.7	The minimum degree of protection provided by the enclosure shall be: — IP 20 for recorders used in heated/air conditioned closed premises or in the cabin of transport vehicles ; — IP 55 for recorders used inside cold enclosures (storage or transport vehicles) and for external sensor ; — IP 65 for recorders used outside buildings or transport vehicles, with sensor inside the cold enclosure.	SL7000 series is IP50 SL50 series is IP55 SL151T is IP66 spYdaq transmitters are IP 65 Cadmus transmitters are IP20 TempMate is IP68

5.10.2.2	Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick frozen food and ice-cream should have the minimum accuracy class 0,5 within the temperature range of −25 °C to + 7 °C. Accuracy class 0,5 states a maximum allowable errors of ±0.5°C with a resolution <0.2°C	All products covered by this declaration meet this requirement. SL52T-A and SL151T-A meet class 0,2 which states a maximum permissible of ±0.2°C and a resolution <0.1°C
5.10.2.3	The manufacturer shall define the recording intervals, periods and storage capacity with its minimum and maximum limits. The maximum time window for calculated temperatures shall be measured with 5 % of the recording interval and a maximum period of 15 min. If there is any possibility of overwriting the recorded values it shall be indicated by the manufacturer.	SL52T has sample rates from 2 seconds to 24 hours. SL151T has sample rates from 30 seconds to 24 hours TempMate has a fixed sample rate of 10 minutes. SpYdaq has a sample rate of 10 minutes. Cadmus reads every minute and uploads to the cloud at programmable intervals from 5 minutes to 24 hours. The operator is made aware of any settings that could overwrite any stored values.
5.10.2.5	The response time shall be: — For recorders with external air sensors maximum 5 min; — For recorders with internal sensors maximum 20 min. The response time is the time needed for the recorded value to reach 90 % of the actual change of applied temperature in the conditions mentioned in 6.4.	All data loggers covered by this declaration meet the requirements.
5.10.3.2	The equipment shall withstand vibration from 5Hz to 8.6 Hz 10mm amplitude and 8.6Hz to 150 Hz acceleration of 3g	All loggers are designed to comply with this requirement