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OMKA-OMEGA ÖLÇME KONTROL SİSTEMLERİ
LABORATUVAR CİHAZLARI SAN. TİC. LTD. ŞTİ.

TEST AND ANALYSIS LABORATORIES

MOD 93/42/EEC DIRECTIVE ANNEX VII

MANUAL TOURNIQUET

Report No: **OMKA – 150522GK01**
Report Date: 17.05.2022
Test Date: 13.05.2022

1348 Sokak No. 5 / 401 Teknik Malzeme İş Merkezi, Çatı Katı, 35110 Yenişehir
İZMİR
Tel : +90.232.459 6263 Faks: +90.232.458 8988

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Introduction

This report has been given by Omega Laboratory after receiving samples of tourniquet from Elmaslar İmalat Tıbbi Cihazlar İnş. Taş. İth. İhr. San. Ve Tic. A.Ş.

Tests and measurements have been done in accordance with the MOD 93/42/EEC Directive.

Our report contains the limit values of the relevant international standard, the specifications of the measuring device, and the measurement method.

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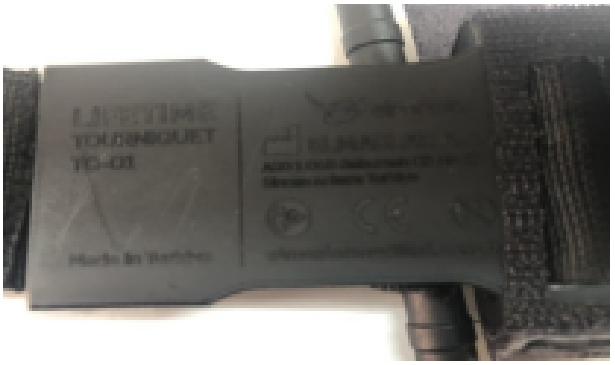
1.1. MEASURING DEVICES
Freezer
Weight disks
Manometer
Steel ruler

1.2. MATERIAL MEASURED
“LIFETIME” labeled “TOURNIQUET TQ-03” on the user manual and branded “TOURNIQUET TQ-01” * on the plastic part, produced by Elmaslar İmalat Tıbbi Cihazlar İnş. Taş. İth. İhr. San. Ve Tic. A.Ş.


** Manufacturer informed that model TQ-03 has the labeling TQ-01 on the plastic part, due to a usage of the same molding of TQ-01 model for manufacturing this part.*

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1.3. MEASUREMENTS

Our staff has selected three samples following the Annex-2 article of the MOD 93/42/EEC directive, and the breaking tests of the products were carried out. The connection parts of equipment: windlass rod, windlass fastening clip, and buckle of the relevant product have been tested with 25% more (50 kg) than 40 kg, which is the force that a standard person can apply. As a result of the test, it was observed that the connection parts of the equipment did not break at ambient temperature, only an instant change occurred in its form, and when the force applied to the product was terminated, it returned to its former condition.

The exact test was repeated at -24 °C while the connection parts of the equipment were kept under -30°C for 6 hours, and there was no breakage in the same way, and it returned to its former form at the end of the test.

There was no change in the product form of the strap, and it kept standing in the same way after 50 kg force was applied to the strap, and a difference in its formation was observed after 12 hours without any change.

The exact test was repeated at -24 °C while the connection types of equipment were kept under -30°C for 6 hours, and there was no change in the product form.

We have tested each tourniquet with calibrated monometer in our test setup. Results show that with one hand usage and turning the windlass rod 4 times, the pressure quickly reaches the value of 50 kPa (0.5 bar). The relevant directive declares this pressure value enough to stop blood pressure and oxygen passage. Additionally after turning the windlass rod 6 times in total, the pressure can reach the value of 80 kPa (0.8 bar).

Also, it was observed that after the 2 hours specified by the same directive, it did not go below the maximum pressure loss level of 2%, and after 12 hours, the pressure loss in the samples was 1% (0.5 kPa, approx 0.05 bar)

The exact test was repeated at -24 °C while the connection types of equipment were kept under -30°C for 6 hours, and pressure loss was recorded as 1.6% (0.8 kPa, about 0.1 bar)

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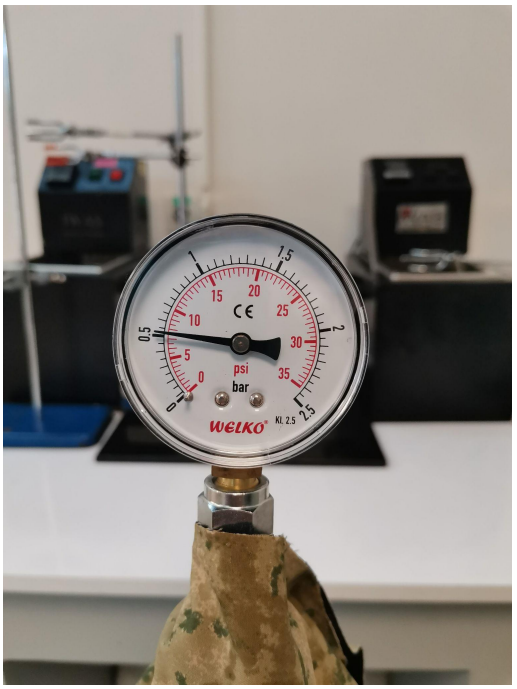

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CONCLUSION: On May 13, 2022, “LIFETIME” brand “TOURNIQUET TQ-03” produced by Elmaslar İmalat Tıbbi Cihazlar İnş. Taş. İth. İhr. San. Ve Tic. A.Ş. was selected and tested. We declared that the measurement results given above are within the measurement limits as stated in the Annex-2 article of the MOD 93/42/EEC directive. All test samples comply with standard conditions.

Technical Staff **Gürcan KAPTANOĞLU** **Signature**	**Laboratory Manager** **Serap KÖKTAŞ KOCA** **Signature**

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