

*Anexa nr. 1*  
*La Procedurile administrative pentru notificarea*  
*dispozitivelor medicale care dețin marcajul CE*  
Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**  
pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
nr. .... din .....

Solicitantul **AELO GRUP SRL**, cu sediul **mun.Chișinău, str.Mitropolit Petru**  
**Movila 23/5, ap.6,**  
tel./fax: **+373 61 033 993/022 60 14 91**, e-mail: **aelogrup@gmail.com**,  
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor  
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție  
pe piață a:

CARONE TRANSPORT STRETCHER- GMDN 35892

Se anexează următoarele acte:  
Declaratie proprie raspundere;Scrisoarea de  
autorizare;Formular Excel;Decalaratie de conformitate;  
ISO.

Data 27.09.2023

Semnătura \_\_\_\_\_

**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

|                                                                                                 |  |
|-------------------------------------------------------------------------------------------------|--|
| Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului |  |
| Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)    |  |
| Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului                    |  |
| Semnătura persoanei responsabile                                                                |  |

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAȚIE PE PROPRIE RĂSPUNDERE**

**Solicitant: Aelo Grup SRL,**

**cu sediul în: mun.Chișinău, str.Mitropolit Petru Movila 23/5, ap,6**

declar pe proprie răspundere, cunoscând prevederile art. **352<sup>1</sup>**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

CARONE TRANSPORT STRETCHER- GMDN 35892

**Se anexează următoarele acte:**

**Formular de Notificare;Scrisoarea de autorizare;Formular Excel;Decalaratie de conformitate; ISO.**

**Sunt autentice și corespund realității.**

*Cobzari -Țurcan Rodica*  
*Administrator*

*Semnătura* \_\_\_\_\_

*Data 27.09.2023*



Rüstü  
Üzümcü

Üzümcü Hastane Ekipmanları  
Metal İşleme Sanayi ve Ticaret AŞ

We, Üzümcü Hospital Equipment Metal Processing Industrial and Trade Company,

based in Türkiye Oğulbey Neighborhood, Kumludere Street No: 1 Gölbaşı/ANKARA, assign Aelo Grup SRL, based in Str Mitropolit Petru Movila 23/5, of.3, Chisinau MD -2004, Moldova, as **authorized representative** in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Ankara,TÜRKİYE

Date: 27.09.2023

Signed:

Tuğçe YADİGAR

International Marketing Specialist



| Nr. | Catalog number (reference)* | Generic name (device name) | Commercial name (brand)*                                                | Model  | Number GMDN* |
|-----|-----------------------------|----------------------------|-------------------------------------------------------------------------|--------|--------------|
| 1   | TRANSPORT STRETCHER         | CARONE TRANSPORT STRETCHER | Üzümcü Hospital Equipment Metal Processing Industrial and Trade Company | CARONE | 35892        |

Semnăt Aelo Grup SRL \_\_\_\_\_  
Administrator Cobzari Țurcan Rodica



## EU DECLARATION OF CONFORMITY

**COMPANY NAME:** ÜZÜMCÜ HOSPITAL EQUIPMENT METAL PROCESSING INC.

**ADDRESS:** Oğulbey Neighbourhood Kumludere Street No:1 Gölbaşı/Ankara/Türkiye

**UDI-DI NUMBER:** 868322909950011VT

**PHONE:** 0 312 444 71 51

We declare that the following Class-1 Other products are in compliance with the provisions of Council Directive MDR 2017/745/EU for medical devices. All supporting documents are stored at the manufacturer's premises. We declare that we will fulfill the obligations imposed by the quality system and that we will keep the quality system adequate and effective.

We declare that we will integrate and update a systematic procedure to review our experience with devices at the post-production stage and apply appropriate tools to implement the necessary corrective measures, including the provisions set out in Annex IV.

### Applicable Standards:

See the list of applicable (compliant) standards in the Technical Documentation

**Approved by** : Batuhan Gökhan Gürsoy  
**Title** : General Manager  
**Approval Date** : 23.06.2021  
Üzümcü Hospital Equipment Metal  
**Approval Place** : Processing Inc.  
**Declaration Revision**  
**No** : 07  
**Declaration Revision**  
**Date** : 20.06.2022

**Signature**

| NO | PRODUCT NAME                                                                      | PRODUCT CODE |
|----|-----------------------------------------------------------------------------------|--------------|
| 1  | OPERATING ROOM CEILING LAMP, DOUBLE, WITH CAMERA                                  | CL-620       |
| 2  | OPERATING ROOM CEILING LAMP, 68LED, WITH MONITOR                                  | CL-6M        |
| 3  | OPERATING ROOM CEILING LAMP WITH CAMERA AND MONITOR                               | CL-6CM       |
| 4  | OPERATING ROOM CEILING LAMP, DOUBLE, CAMERA, MONITOR                              | CL-620CM     |
| 5  | OPERATING ROOM CEILING LAMP, DOUBLE, CAMERA, MONITOR                              | CL-660CM     |
| 6  | OPERATING ROOM CEILING LAMP, SINGLE                                               | CL-6D        |
| 7  | OPERATING ROOM CEILING LAMP, DOUBLE, WITH SATELLITE HEAD                          | CL-62D       |
| 8  | OPERATING ROOM CEILING LAMP, TRIPLE                                               | CL-662D      |
| 9  | OPERATING ROOM CEILING LAMP, SINGLE, 28 LED                                       | CL-2D        |
| 10 | OPERATING ROOM CEILING LAMP, DOUBLE                                               | CL-66D       |
| 11 | EXAMINATION LAMP                                                                  | DL-700L      |
| 12 | EXAMINATION LAMP                                                                  | DL-450L      |
| 13 | EXAMINATION LAMP                                                                  | DL-400L      |
| 14 | OPERATING TABLE MOBILE POLYURETHANE                                               | OPT-200P     |
| 15 | OPERATING TABLE VISCO CUSHION, PATIENT HEATED                                     | OPT-200V     |
| 16 | OPERATING TABLE KIDNEY MOVING                                                     | OPM-600N     |
| 17 | OPERATING TABLE BARIATRIC SURGERY                                                 | OPM-600L     |
| 18 | OPERATING TABLE                                                                   | OPM-200M     |
| 19 | IMAGING TABLE SINGLE LEGS                                                         | C-IMAGE-01   |
| 20 | IMAGING TABLE DOUBLE LEGS                                                         | C-IMAGE-02   |
| 21 | GYNECOLOGY EXAMINATION TABLE                                                      | GT-5F        |
| 22 | OPERATING TABLE ACCESSORIES ORTHOPEDIC TRACTION SET                               | OPM-555      |
| 23 | OPERATING TABLE ACCESSORIES NEUROSURGERY HEADREST WITH PIN AND HORSESHOE HEADREST | OPM-222      |
| 24 | OPERATING TABLE ACCESSORIES HORSEHOE HEAD SUPPORT                                 | OPM-223      |
| 25 | OPERATING TABLE ACCESSORIES ARTHROSCOPY SHOULDER SUPPORT                          | OPM-333      |
| 26 | OPERATING TABLE ACCESSORIES LEG POSITIONING BOOTS                                 | OPM-666      |
| 27 | OPERATING TABLE ACCESSORIES ARM SUPPORT                                           | OPM-120      |
| 28 | OPERATING TABLE ACCESSORIES ANESTHESIA SCREEN AND STAND                           | OPM-100      |

|    |                                           |         |
|----|-------------------------------------------|---------|
| 29 | BODY STRAP                                | OPM-150 |
| 30 | GYNECOLOGY KNEE CRUTCH (PAIR)             | OPM-220 |
| 31 | IRRIGATION BOWL                           | OPM-380 |
| 32 | HEAD REST CROSSBAR                        | OPM-300 |
| 33 | CLAMP                                     | OPM-405 |
| 34 | CLAMP                                     | OPM-390 |
| 35 | CARBON FIBER EXTENSION                    | OPM-355 |
| 36 | SHOULDER/LATERAL SUPPORT                  | OPM-135 |
| 37 | FOOT-WRIST STRAP                          | OPM-155 |
| 38 | FOOT SUPPORT (PAIR)                       | OPM-200 |
| 39 | PROCTOLOGICAL ACCESSORIES                 | OPM-310 |
| 40 | EXTENTION LEG PLATE (SINGLE)              | OPM-255 |
| 41 | X-RAY CASSETTE HOLDER                     | OPM-330 |
| 42 | ACCESSORY TROLLEY                         | OPM-995 |
| 43 | KNEE ARTHROSCOPY SUPPORT                  | OPM-240 |
| 44 | MENISCUS POSITIONING ROLL                 | OPM-250 |
| 45 | ARM SURGERY PLATE                         | OPM-365 |
| 46 | ORTHOPEDIC TRACTION SET ACCESSORY TROLLEY | OPM-550 |
| 47 | OPHTHALMOLOGY HEAD SUPPORT                | OPM-270 |
| 48 | WEINBERGER HAND TRACTION SET              | OPM-275 |
| 49 | GYNECOLOGY PROBE                          | G01     |
| 50 | GYNECOLOGY PROBE                          | G02     |
| 51 | GYNECOLOGY PROBE                          | G03     |
| 52 | NEGATOSCOPE SINGLE                        | 95001   |
| 53 | NEGATOSCOPE DUAL                          | 95002   |
| 54 | NEGATOSCOPE TRIPLE                        | 95003   |
| 55 | IV STAND WITH ACCESSORY BASKET            | 70715   |
| 56 | IV STAND                                  | 70710   |
| 57 | SILICONE BIRTH CUP 50MM                   | DC-50   |
| 58 | SILICONE BIRTH CUP 60MM                   | DC-60   |
| 59 | SILICONE BIRTH CUP 70MM                   | DC-70   |
| 60 | ASPIRATION HOSE                           | MGH     |

|    |                                                                            |         |
|----|----------------------------------------------------------------------------|---------|
| 61 | RESPONSE LAMP                                                              | CL-2MB  |
| 62 | DOUBLE JOINT RAIL TYPE IV STAND                                            | 3030.AK |
| 63 | MAYO TABLE HYDRAULIC                                                       | 24001   |
| 64 | MAYO TABLE MECHANICAL                                                      | 24060   |
| 65 | RESPONSE LAMP                                                              | CL-6MB  |
| 66 | H TYPE IV STAND                                                            | 3050.AA |
| 67 | OPERATING TABLE ACCESSORIES NAIL HEAD                                      | OPM-224 |
| 68 | OPERATING TABLE POLYURETHANE GENERAL SURGERY                               | ST-2P   |
| 69 | OPERATING TABLE VISCO CUSHION GENERAL SURGERY                              | ST-2V   |
| 70 | OPERATING TABLE GENERAL SURGERY RENAL ACTION<br>POLYURETHANE               | ST-6N   |
| 71 | ORTHOPEDIC TRACTION SET                                                    | ST-55   |
| 72 | OPERATING TABLE BARIATRIC SURGERY                                          | BAM-01  |
| 73 | PIN HEADREST AND HORSESHOE HEAD SUPPORT                                    | ST-22   |
| 74 | ARTHROSCOPY SHOULDER SUPPORT                                               | ST-33   |
| 75 | IMAGING TABLE SINGLE LEGS                                                  | IMT-01  |
| 76 | IMAGING TABLE DOUBLE LEGS                                                  | IMT-02  |
| 77 | GYNECOLOGICAL EXAMINATION TABLE                                            | JIM-5F  |
| 78 | OPERATING ROOM CEILING LAMP WITH 3 ARMS CAMERA AND<br>MONITOR              | MEL-2KM |
| 79 | OPERATING ROOM CEILING LAMP 3 ARMS                                         | MEL-3   |
| 80 | OPERATING ROOM CEILING LAMP 2 ARMS 68 LED                                  | MEL-4   |
| 81 | OPERATING ROOM CEILING LAMP 2 ARMS                                         | MEL-5   |
| 82 | OPERATING ROOM CEILING LAMP WITH 2 ARMS CAMERA AND<br>WALL-MOUNTED MONITOR | MEL-6KM |
| 83 | OPERATING ROOM LAMP WITH MOBILE BATTERY 28 LED                             | MEL-7   |
| 84 | OPERATING ROOM LAMP WITH MOBILE BATTERY 68 LEDS                            | MEL-8   |
| 85 | LED FOOT INSPECTION LAMP                                                   | ML-40   |
| 86 | IV STAND WITH ACCESSORY BASKET                                             | SAS.01  |
| 87 | OPERATING TABLE HAND CONTROL WIRED                                         | OPM-280 |
| 88 | GYNECOLOGICAL EXAMINATION TABLE                                            | GT-4F   |
| 89 | SPINE SURGERY ELEVATION APPARATUS                                          | OPM-281 |
| 90 | SEMI-CYLINDRICAL GEL CUSHION                                               | OPM-282 |

|            |                                                |                             |
|------------|------------------------------------------------|-----------------------------|
| <b>91</b>  | HORSESHOE GEL CUSHION                          | OPM-283                     |
| <b>92</b>  | PATIENT CARE BED                               | OPM-289                     |
| <b>93</b>  | HYDRAULIC MAYO TABLE                           | M-0103                      |
| <b>94</b>  | MECHANIC MAYO TABLE                            | M-0104                      |
| <b>95</b>  | ELECTRICAL PATIENT BED,4 MOTORS                | CHZ 4050                    |
| <b>96</b>  | PEDIATRIC HOSPITAL BED, 3 MOTORS ALUMINUM BASE | EUB 3020                    |
| <b>97</b>  | PEDIATRIC HOSPITAL BED, 2 MOTORS ALUMINUM BASE | EUB 1020                    |
| <b>98</b>  | PEDIATRIC HOSPITAL BED, 2 MOTORS               | BMG 1100                    |
| <b>99</b>  | PEDIATRIC HOSPITAL BED, 3 MOTORS               | BMG 1130                    |
| <b>100</b> | PEDIATRIC HOSPITAL BED, 2 ADJUSTMENTS          | BMG 1120                    |
| <b>101</b> | PEDIATRIC HOSPITAL BED, 2 MOTORS               | BMG 1020                    |
| <b>102</b> | HOSPITAL CRIB & CABINET                        | BAMUS 15                    |
| <b>103</b> | HOSPITAL CRIB & CABINET                        | BAMUS 14                    |
| <b>104</b> | STACKABLE HOSPITAL CRIB                        | BAMUS 12                    |
| <b>105</b> | HOSPITAL CRIB                                  | BAMUS 11                    |
| <b>106</b> | ELECTRICAL OBSTETRIC / DELIVERY BED            | MLISS 1100                  |
| <b>107</b> | PROCEDURAL STRETCHER                           | CARONE Procedural Stretcher |
| <b>108</b> | TRANSPORT STRETCHER                            | CARONE Transport Stretcher  |
| <b>109</b> | TRAUMA STRETCHER                               | CARONE Trauma Stretcher     |
| <b>110</b> | OPERATION ROOM TRANSFER STRETCHER              | DK 140                      |
| <b>111</b> | EMERGENCY CART                                 | MDKL Emergency Cart         |
| <b>112</b> | PROCEDURE CART                                 | MDKL Procedure Cart         |
| <b>113</b> | ANESTHESIA CART                                | MDKL Anesthesia Cart        |
| <b>114</b> | TREATMENT CART                                 | MDKL Treatment Cart         |
| <b>115</b> | EMERGENCY CART                                 | DMT 01 Emergency Cart       |
| <b>116</b> | ANESTHESIA CART                                | DMT 02 Anesthesia Cart      |
| <b>117</b> | TREATMENT CART                                 | DMT 03 Treatment Cart       |
| <b>118</b> | OVERBED TABLE, ABS                             | STS 161                     |
| <b>119</b> | OVERBED TABLE                                  | STS 160                     |

|            |                                                    |                                                               |
|------------|----------------------------------------------------|---------------------------------------------------------------|
| <b>120</b> | OVERBED TABLE                                      | STS 163                                                       |
| <b>121</b> | SPACE SAVER STACKABLE WHEELCHAIR                   | ZM 14                                                         |
| <b>122</b> | EXAMINATION COUCH                                  | MDC 03                                                        |
| <b>123</b> | EXAMINATION COUCH, FOLDABLE                        | MDC 04                                                        |
| <b>124</b> | EXAMINATION COUCH WITH DRAWERS AND CABINET         | MDC 01                                                        |
| <b>125</b> | EXAMINATION COUCH WITH 3 DRAWERS                   | MDC 02                                                        |
| <b>126</b> | PEDIATRIC EXAMINATION COUCH                        | MDC 05                                                        |
| <b>127</b> | STOOL                                              | RU 06                                                         |
| <b>128</b> | STOOL WITH BACKREST                                | RU 07                                                         |
| <b>129</b> | FOLDING SCREEN                                     | AU 14                                                         |
| <b>130</b> | BLOOD DONATION CHAIR, 2 MOTORS                     | UCM 12 Blood Donation Chair, 2<br>Motors                      |
| <b>131</b> | ELECTRIC BLOOD DONATION CHAIR, 4 MOTORS            | CPM 14 Electronic Blood<br>Transfusion Chair, 4 Motors        |
| <b>132</b> | ELECTRIC DIALYSIS AND CHEMOTHERAPY CHAIR, 4 MOTORS | MAS 4 Electronic Dialysis and<br>Chemotherapy Chair, 4 Motors |
| <b>133</b> | ELECTRIC ENT CHAIR, 4 MOTORS                       | RTU 7 Electronic ENT Chair, 4<br>Motors                       |



# CERTIFICATE

## ÜZÜMCÜ HASTANE EKİPMANLARI METAL İŞLEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

OĞULBEY MAHALLESİ KUMLUDERE CADDESİ NO:1  
GÖLBAŞI / ANKARA / TÜRKİYE

*Has been assessed and found to Comply with the Requirements of:*

### ISO 9001:2015

*The Quality Management System is applicable to:*

DESIGN, DEVELOPMENT, MANUFACTURE, ASSEMBLY, DISTRIBUTION AND SERVICE OF OPERATING ROOM EQUIPMENT, INTENSIVE CARE AND EMERGENCY ROOM EQUIPMENT, PATIENT ROOM AND CLINICAL EQUIPMENT, STERILIZATION AND STAINLESS STEEL EQUIPMENT, MEDICAL GAS SYSTEM AND EQUIPMENT, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT

Certificate Number: QMS-13368

Initial Certification Date: 18.03.2021

Certification Period: 3 Years

Certificate Validity Date: 17.03.2024

IQR Sertifikasyon Onayı



ACCREDITED  
Management Systems  
Certification Body  
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



# CERTIFICATE

## ÜZÜMCÜ HASTANE EKİPMANLARI METAL İŞLEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

OĞULBEY MAHALLESİ KUMLUDERE CADDESİ NO:1  
GÖLBAŞI / ANKARA / TÜRKİYE

*Has been assessed and found to Comply with the Requirements of:*

### ISO 13485:2016

*Medical Devices -Quality Management System is applicable to:*

DESIGN, DEVELOPMENT, MANUFACTURE, ASSEMBLY, DISTRIBUTION AND SERVICE OF OPERATING ROOM EQUIPMENT, INTENSIVE CARE AND EMERGENCY ROOM EQUIPMENT, PATIENT ROOM AND CLINICAL EQUIPMENT, STERILIZATION AND STAINLESS STEEL EQUIPMENT, MEDICAL GAS SYSTEM AND EQUIPMENT, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT

Certificate Number: 2021/MDQMS/10102 Initial Certification Date: 18.03.2021

Certification Period: 3 Years

Certificate Validity Date: 17.03.2024

IQR Sertifikasyon Onayı



ACCREDITED  
Management Systems  
Certification Body  
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



# CERTIFICATE

## ÜZÜMCÜ HASTANE EKİPMANLARI METAL İŞLEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

OĞULBEY MAHALLESİ KUMLUDERE CADDESİ NO:1  
GÖLBAŞI / ANKARA / TÜRKİYE

*Has been assessed and found to Comply with the Requirements of:*

### ISO 14001:2015

*The Environmental Management System is applicable to*

DESIGN, DEVELOPMENT, MANUFACTURE, ASSEMBLY, DISTRIBUTION AND SERVICE OF OPERATING ROOM EQUIPMENT, INTENSIVE CARE AND EMERGENCY ROOM EQUIPMENT, PATIENT ROOM AND CLINICAL EQUIPMENT, STERILIZATION AND STAINLESS STEEL EQUIPMENT, MEDICAL GAS SYSTEM AND EQUIPMENT, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT

Certificate Number: EMS-13368

Initial Certification Date: 18.03.2021

Certification Period: 3 Years

Certificate Validity Date: 17.03.2024

IQR Sertifikasyon Onayı



ACCREDITED  
Management Systems  
Certification Body  
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



# CERTIFICATE

## ÜZÜMCÜ HASTANE EKİPMANLARI METAL İŞLEME SANAYİ VE TİCARET ANONİM ŞİRKETİ

OĞULBEY MAHALLESİ KUMLUDERE CADDESİ NO:1  
GÖLBAŞI / ANKARA / TÜRKİYE

*Has been assessed and found to comply with the requirements of:*

### ISO 45001:2018

*The Occupational Health and Safety Management System is applicable to:*

DESIGN, DEVELOPMENT, MANUFACTURE, ASSEMBLY, DISTRIBUTION AND SERVICE OF OPERATING ROOM EQUIPMENT, INTENSIVE CARE AND EMERGENCY ROOM EQUIPMENT, PATIENT ROOM AND CLINICAL EQUIPMENT, STERILIZATION AND STAINLESS STEEL EQUIPMENT, MEDICAL GAS SYSTEM AND EQUIPMENT, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT

Certificate Number: OHSMS-00112452

Initial Certification Date: 03.03.2023

Certification Period: 3 Years

Certificate Validity Date: 02.03.2024



IQR Sertifikasyon Onayı



ACCREDITED  
Management Systems  
Certification Body  
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com