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| <p>DECLARATION OF</p> <p>EC</p> <p>CONFORMITY</p> |
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WE :Name of Manufacturer :**EF MEDICA SRL**Address of Manufacturer :**Via Pillhof, 25
39057 Frangarto (BZ)
ITALY**

Hereby declare, that the product:

Name of product :

Recording charts for medical equipment

Product code :

as per annex I

Classification(as per Annex IX, 93/42/EEC) :Device of class " I " with measuring function
GMDN: 15-639

Conforms to the MDD 93/42/EEC Council Directives and subsequent amendments,

Does not contain neither medicinal substances nor elements of animals

That the procedure for the assessment of conformity described in Annex VII of the abovementioned Directive has been followed

As mentioned on the EC certificate nr. CE 954/MDD issued by IMQ (O.N. nr. 0051)

That the procedures of the quality management system EF Medica have been followed according to ISO 13485, Certificate of Registration Nr. 9124.EFMD issued by IMQ

And that it does not contain latex.

Frangarto, 04.07.2019



Andrea Filippi -
Quality responsible

ANNEX I OF THE EC DECLARATION OF CONFORMITY FOR RECORDING CHARTS FOR MEDICAL EQUIPMENT

ITEM CODES:

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|-----------|-----------|-----------|-----------|------------|------------|-----------|-----------|
| 96365 | 10.057.15 | 10.080.08 | 10.112.13 | 10.188.01 | 11.120.01 | 20.063.01 | 20.110.14 |
| 10.042.01 | 10.057.17 | 10.080.09 | 10.112.16 | 10.210.01 | 11.120.02 | 20.063.02 | 20.110.15 |
| 10.045.01 | 10.058.01 | 10.080.10 | 10.112.18 | 10.210.02 | 11.120.03 | 20.063.03 | 20.110.18 |
| 10.045.02 | 10.058.03 | 10.080.14 | 10.112.19 | 10.210.03 | 11.120.04 | 20.063.04 | 20.111.01 |
| 10.045.03 | 10.058.05 | 10.080.15 | 10.113.01 | 10.210.04 | 11.120.05 | 20.063.05 | 20.111.02 |
| 10.049.01 | 10.058.06 | 10.080.16 | 10.114.05 | 10.210.05 | 11.120.06 | 20.063.06 | 20.112.01 |
| 10.049.02 | 10.058.07 | 10.080.17 | 10.118.01 | 10.210.06 | 11.120.07 | 20.063.07 | 20.112.02 |
| 10.050.01 | 10.058.08 | 10.090.01 | 10.120.01 | 10.210.07 | 11.130.01 | 20.063.08 | 20.112.03 |
| 10.050.02 | 10.058.10 | 10.090.02 | 10.120.02 | 10.210.08 | 11.130.02 | 20.063.09 | 20.112.05 |
| 10.050.03 | 10.058.11 | 10.090.03 | 10.120.03 | 10.210.09 | 11.134.01 | 20.063.10 | 20.112.07 |
| 10.050.04 | 10.058.12 | 10.092.01 | 10.123.01 | 10.210.10 | 11.134.02 | 20.070.01 | 20.112.08 |
| 10.050.05 | 10.058.16 | 10.092.02 | 10.125.01 | 10.210.14 | 11.134.03 | 20.080.01 | 20.112.09 |
| 10.050.07 | 10.060.01 | 10.092.03 | 10.125.03 | 10.215.01 | 11.134.04 | 20.080.02 | 20.112.10 |
| 10.050.08 | 10.060.02 | 10.100.02 | 10.125.04 | 10.215.02 | 11.134.05 | 20.080.03 | 20.112.11 |
| 10.050.11 | 10.060.05 | 10.100.03 | 10.126.02 | 10.215.02A | 11.140.01 | 20.080.04 | 20.112.12 |
| 10.050.12 | 10.060.07 | 10.100.04 | 10.126.03 | 10.215.03 | 11.140.02 | 20.080.05 | 20.112.13 |
| 10.050.14 | 10.060.08 | 10.100.06 | 10.130.01 | 10.215.04 | 11.145.01 | 20.080.06 | 20.112.15 |
| 10.050.16 | 10.060.09 | 10.104.01 | 10.130.02 | 10.215.05 | 11.145.04 | 20.080.07 | 20.112.16 |
| 10.050.18 | 10.060.10 | 10.104.02 | 10.130.03 | 10.215.08 | 11.151.01 | 20.080.08 | 20.112.17 |
| 10.050.19 | 10.060.11 | 10.105.01 | 10.130.04 | 10.216.02 | 11.209.01 | 20.080.09 | 20.112.18 |
| 10.050.20 | 10.060.14 | 10.106.02 | 10.130.05 | 10.216.03 | 11.209.02 | 20.080.10 | 20.112.19 |
| 10.050.23 | 10.060.15 | 10.108.01 | 10.135.01 | 10.216.04 | 11.210.01 | 20.090.01 | 20.112.20 |
| 10.050.24 | 10.060.17 | 10.108.02 | 10.135.02 | 10.216.05 | 11.210.02 | 20.090.02 | 20.112.21 |
| 10.050.26 | 10.060.18 | 10.108.03 | 10.136.01 | 10.216.06 | 11.215.01 | 20.090.03 | 20.112.22 |
| 10.050.28 | 10.060.19 | 10.108.04 | 10.142.01 | 10.216.07 | 11.216.01 | 20.090.04 | 20.112.24 |
| 10.050.29 | 10.060.20 | 10.109.02 | 10.144.01 | 10.216.08 | 20.050.01 | 20.090.05 | 20.112.26 |
| 10.050.31 | 10.063.01 | 10.110.02 | 10.144.02 | 10.241.01 | 20.050.02 | 20.090.06 | 20.112.27 |
| 10.050.32 | 10.063.02 | 10.110.10 | 10.144.03 | 10.250.01 | 20.050.03 | 20.090.07 | 20.112.28 |
| 10.050.34 | 10.063.05 | 10.110.19 | 10.144.04 | 10.250.02 | 20.050.03A | 20.090.08 | 20.112.29 |
| 10.050.35 | 10.063.06 | 10.110.22 | 10.144.05 | 10.278.01 | 20.050.03B | 20.100.01 | 20.114.01 |
| 10.050.36 | 10.063.08 | 10.110.23 | 10.144.06 | 10.280.01 | 20.050.04 | 20.100.02 | 20.114.02 |
| 10.050.38 | 10.063.09 | 10.110.25 | 10.144.07 | 10.603.03 | 20.050.06 | 20.100.03 | 20.114.03 |
| 10.050.39 | 10.063.11 | 10.110.27 | 10.144.08 | 11.050.01 | 20.050.07 | 20.104.01 | 20.114.04 |
| 10.050.41 | 10.063.12 | 10.110.29 | 10.145.01 | 11.050.02 | 20.050.12 | 20.106.01 | 20.114.05 |
| 10.050.42 | 10.063.14 | 10.110.30 | 10.145.02 | 11.050.03 | 20.050.13 | 20.106.02 | 20.114.06 |
| 10.050.43 | 10.075.01 | 10.110.31 | 10.145.03 | 11.050.04 | 20.050.14 | 20.108.01 | 20.114.08 |
| 10.055.01 | 10.075.06 | 10.112.03 | 10.148.01 | 11.050.05 | 20.050.15 | 20.110.01 | 20.120.01 |
| 10.055.03 | 10.080.03 | 10.112.04 | 10.152.01 | 11.050.06 | 20.050.16 | 20.110.07 | 20.120.02 |
| 10.055.08 | 10.080.04 | 10.112.07 | 10.161.00 | 11.050.07 | 20.060.01 | 20.110.09 | 20.120.03 |
| 10.057.03 | 10.080.05 | 10.112.08 | 10.183.01 | 11.060.01 | 20.060.02 | 20.110.10 | 20.120.04 |
| 10.057.06 | 10.080.07 | 10.112.12 | 10.183.02 | 11.060.02 | 20.060.03 | 20.110.11 | 20.120.06 |

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|-----------|------------|------------|-----------|-----------|
| 20.120.08 | 20.210.03A | 20.210.59 | 20.215.02 | 21.210.03 |
| 20.120.09 | 20.210.04 | 20.210.61 | 20.215.03 | 21.210.04 |
| 20.120.16 | 20.210.05 | 20.210.62 | 20.215.04 | 21.210.05 |
| 20.120.17 | 20.210.06 | 20.210.64 | 20.215.08 | 21.210.06 |
| 20.126.02 | 20.210.07 | 20.210.65 | 20.215.09 | 21.210.07 |
| 20.126.06 | 20.210.10 | 20.210.66 | 20.215.10 | 21.210.08 |
| 20.130.01 | 20.210.11 | 20.210.71 | 20.215.11 | 21.210.09 |
| 20.130.02 | 20.210.12 | 20.210.72 | 20.215.12 | 21.210.10 |
| 20.130.03 | 20.210.13 | 20.210.74 | 20.215.13 | 21.210.11 |
| 20.130.04 | 20.210.14 | 20.210.75 | 20.215.15 | 21.210.12 |
| 20.130.05 | 20.210.15 | 20.210.76 | 20.215.16 | 21.210.13 |
| 20.134.01 | 20.210.17 | 20.210.77 | 20.215.17 | 21.210.14 |
| 20.134.02 | 20.210.19 | 20.210.80 | 20.215.18 | 21.210.15 |
| 20.135.01 | 20.210.20 | 20.210.81 | 20.215.20 | 21.214.01 |
| 20.140.01 | 20.210.21 | 20.210.83 | 20.215.21 | 21.215.01 |
| 20.144.01 | 20.210.22 | 20.210.84 | 20.215.22 | 21.215.02 |
| 20.144.02 | 20.210.23 | 20.210.85 | 20.215.23 | 21.215.03 |
| 20.144.03 | 20.210.23A | 20.210.86 | 20.215.24 | 21.215.05 |
| 20.144.05 | 20.210.24 | 20.210.87 | 20.216.01 | 21.215.06 |
| 20.144.06 | 20.210.26 | 20.210.88 | 20.216.02 | 21.216.06 |
| 20.144.07 | 20.210.28 | 20.210.89 | 20.216.05 | 21.216.07 |
| 20.144.09 | 20.210.29 | 20.210.90 | 20.216.06 | 22.120.01 |
| 20.145.01 | 20.210.30 | 20.210.91 | 20.216.07 | 22.210.02 |
| 20.145.02 | 20.210.32 | 20.210.92 | 20.216.09 | 22.240.03 |
| 20.145.03 | 20.210.33 | 20.210.93 | 20.216.11 | 22.245.01 |
| 20.145.04 | 20.210.34 | 20.210.94 | 20.216.17 | 22.245.02 |
| 20.148.01 | 20.210.35 | 20.210.95 | 20.216.20 | 22.250.01 |
| 20.150.01 | 20.210.36 | 20.210.96 | 20.216.21 | 22.250.03 |
| 20.150.02 | 20.210.37 | 20.210.98 | 20.220.02 | 22.345.02 |
| 20.150.03 | 20.210.38 | 20.210.100 | 20.297.01 | 22.420.04 |
| 20.150.04 | 20.210.39 | 20.210.101 | 20.297.02 | |
| 20.151.01 | 20.210.40 | 20.210.102 | 20.401.01 | |
| 20.152.03 | 20.210.41 | 20.210.103 | 21.075.01 | |
| 20.152.04 | 20.210.42 | 20.210.104 | 21.100.01 | |
| 20.152.05 | 20.210.43 | 20.210.105 | 21.141.01 | |
| 20.152.06 | 20.210.44 | 20.210.106 | 21.141.02 | |
| 20.156.01 | 20.210.45 | 20.210.107 | 21.146.01 | |
| 20.170.01 | 20.210.46 | 20.210.108 | 21.150.01 | |
| 20.170.02 | 20.210.48 | 20.210.109 | 21.150.02 | |
| 20.183.01 | 20.210.49 | 20.210.110 | 21.150.03 | |
| 20.183.02 | 20.210.50 | 20.210.111 | 21.151.01 | |
| 20.183.03 | 20.210.51 | 20.210.112 | 21.152.01 | |
| 20.200.01 | 20.210.52 | 20.210.113 | 21.152.02 | |
| 20.207.01 | 20.210.53 | 20.210.114 | 21.152.03 | |
| 20.207.02 | 20.210.54 | 20.210.115 | 21.152.04 | |
| 20.210.01 | 20.210.55 | 20.210.116 | 21.152.05 | |
| 20.210.02 | 20.210.56 | 20.215.01 | 21.210.01 | |
| 20.210.03 | 20.210.57 | 20.215.01A | 21.210.02 | |