The European Association of Medical devices Notified Bodies

Medical Device Survey 2021
Data from all members (end 2021)
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❖ Valid certificates at end of 2021

- Total: 19,906

- Numbers of certificate by 30 NBs:
  - > 1,000: 6 NBs
  - 350 - 1,000: 10 NBs
  - < 350: 14 NBs

- Average: 664
- Median: 406
Valid CE certificates issued from 2010 to 2021

> 1500 certificates thanks to new members

Valid CE certificates issued from 2010 to 2021.
Distribution of certificates between different directives

- MDD (92%)
- AIMDD (2%)
- IVDD (6%)
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Distribution between different conformity assessment modules under AIMDD

- Annex 2: 89%
- Annex 3: 9%
- Annex 4: 0%
- Annex 5: 3%
Distribution between different conformity assessment modules under MDD

- Annex II (excluding point 4): 52%
- Annex V: 22%
- Annex IV: 2%
- Annex VI: 0%
- EC design examination: 22%
- EC design examination with drug consultation: 2%
Distribution between different conformity assessment modules under IVDD

- Annex IV: 86%
- Annex III: 12%
- Annex VII: 2%
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- New directives certificates issued in 2021 - mainly renewals

- Total: 5,157
- Average: 171.9
- Median: 42
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New CE certificates issued from 2010 to 2021

![Chart showing new CE certificates issued from 2010 to 2021. The chart displays the total and average number of certificates issued each year, with the highest number of certificates issued in 2021.

- 2010: 6,993
- 2012: 5,061
- 2013: 4,480
- 2014: 3,847
- 2015: 4,098
- 2016: 5,591
- 2017: 5,157
- 2018: 5,591
- 2019: 5,591
- 2020: 5,591
- 2021: 5,591

Total Average

- 2010: 6,993
- 2012: 111
- 2013: 181
- 2014: 181
- 2015: 204
- 2016: 195
- 2017: 160
- 2018: 215
- 2019: 323
- 2020: 215
- 2021: 172

Team-NB-MD-Survey-2021
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Distribution between different directives in 2021

- MDD: 87%
- IVD: 12%
- AIMDD: 1%
Distribution between different conformity assessment modules under AIMDD in 2021

- Annex 2: 92.9%
- Annex 3: 5.4%
- Annex 4: 0.0%
- Annex 5: 1.8%
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Distribution between different conformity assessment modules under MDD in 2021

- EC design examination: 24.0%
- Annex II (excluding point 4): 52.4%
- Annex V: 21.8%
- Annex VI: 0.3%
- Annex IV: 0.1%
- Annex III: 0.4%
- EC design examination with drug consultation: 0.9%
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- Distribution between different conformity assessment modules under IVDD in 2021

- Annex IV: 89%

- Annex VII: 5%

- Annex III: 6%
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- Distribution of certificates between different regulations

**Distribution of Certificates**

- **MDR**
  - 892
  - 89%

- **IVDR**
  - 110
  - 11%
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Distribution of certificates between different conformity assessment modules under MDR

- Annex IX - Ch I & III: 69%
- Annex IX - Ch II: 21%
- Annex IX - Specific additional procedure: certificates requiring consultations of medicines authorities/EMA (rules 14)?: 0%
- Annex X: 0%
- Annex XI - part A: 10%
- Annex XI - part B: 0%

5.6% MDR certificates issued in comparison with total valid AIMDD + MDD certificates at end 2021
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**Distribution between different conformity assessment modules under IVDR**

- Annex IX.5.2. - Companion diagnostics (consultations of medicines authorities/EMA)?
  - 0%
- Annex X
  - 0%
- Annex XI
  - 0%
- Annex IX - Ch II
  - 57%
- Annex IX - Ch I & III
  - 43%

**2,7% IVDR certificates issued in comparison with total valid IVDD certificates at end 2021**
### Medical Device Survey 2021

#### Comparison of issued certificates among Regulations

<table>
<thead>
<tr>
<th>Year</th>
<th>MDR</th>
<th>IVDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>180</td>
<td>9</td>
</tr>
<tr>
<td>2021</td>
<td>110</td>
<td>892</td>
</tr>
</tbody>
</table>

- 5 fold increase in issuance of Regulations certificates between 2020 and 2021
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Distribution of applications between different regulations

- **MDR**: 4,666 (89%)
- **IVDR**: 604 (11%)

23.3% of regulations applications received at end 2021 in comparison with total valid certificates.
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Distribution of applications between different conformity assessment modules under MDR

- Annex IX - Specific additional procedure: certificates requiring consultations of medicines authorities/EMA (rules 14)?
  - 2%
- Annex IX - Ch II
  - 39%
- Annex IX - Ch I & III
  - 57%
- Annex XI - part A
  - 2%
- Annex X
  - 0%
- Annex XI - part B
  - 0%

26.3% MDR applications received at end 2021 in comparison with total valid AIMDD + MDD certificates
Distribution of applications between different conformity assessment modules under IVDR

- Annex IX.5.2. - Companion diagnostics (consultations of medicines authorities/EMA) 2%
- Annex X 0%
- Annex XI 0%
- Annex IX - Ch I & III 43%
- Annex IX - Ch II 55%

14.9% IVDR applications received at end 2021 in comparison with total valid IVDD certificates
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Comparison of received applications against regulations

64% increase in receipt of applications against Regulations between 2020 and 2021

Time flies: Still a lot of application to be received
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Average time to reach issuance of a NEW (not renewal) EC certificate

- less than 6 months: 1 (4%)
- 6 - 12 months: 12 (43%)
- 13 - 18 months: 11 (39%)
- 19 - 24 months: 4 (14%)
- > 24 months: 0%
Completeness check

Activity to ensure that complete technical documentation has been received before undertaking the review of its content

Below graph with deemed satisfactory submissions (no request for any additional information)

⚠️ On the basis of the NBs already doing the check (81%).

[Not yet applied by 5 NBs (19%) as not yet designated against regulations]

七十周年 of notified bodies indicate that at least half of the TD submitted are deemed incomplete, and request additional information to start the assessment.

Legend
1st line: Level of completeness check (<25% - 25-50% - 51-75% - >75%)
2nd line: number of NBs responding
3rd line: percentage of the technical documentation completion
Valid certificates against ISO 13485

- Total: 18,349
- Average: 612
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Valid certificates against ISO 13485 from 2010 to 2021:

- 2010 (19 NBs)
- 2012 (28 NBs)
- 2013 (28 NBs)
- 2014 (25 NBs)
- 2015 (22 NBs)
- 2016 (21 NBs)
- 2017 (24 NBs)
- 2018 (23 NBs)
- 2019 (23 NBs)
- 2020 (26 NBs)
- 2021 (30 NBs)

Total Average

Chart showing the number of valid certificates against ISO 13485 from 2010 to 2021 for different years and the total and average number of certificates.
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Number of certificates withdrawn in 2021

Reasons for withdrawing:
- cessation of activity - cancelled
- due to end of Directives - contractual obligations not fulfilled, financial issues - not closing the NCs - negative assessment result - Customer refuses audit or contact not possible - No longer manufacturing product liquidations - change of NB - unannounced audits not satisfactory

Total: 1.002
Average: 33
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- **Number of certificates withdrawn from 2010 to 2021**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>244</td>
<td>1.058</td>
</tr>
<tr>
<td>2012</td>
<td>915</td>
<td>1.294</td>
</tr>
<tr>
<td>2013</td>
<td>881</td>
<td>1.058</td>
</tr>
<tr>
<td>2014</td>
<td>1.043</td>
<td>1.058</td>
</tr>
<tr>
<td>2015</td>
<td>957</td>
<td>1.058</td>
</tr>
<tr>
<td>2016</td>
<td>883</td>
<td>1.058</td>
</tr>
<tr>
<td>2017</td>
<td>1.002</td>
<td>1.058</td>
</tr>
<tr>
<td>2018</td>
<td>1.043</td>
<td>1.058</td>
</tr>
<tr>
<td>2019</td>
<td>33</td>
<td>1.058</td>
</tr>
<tr>
<td>2020</td>
<td>56</td>
<td>1.058</td>
</tr>
<tr>
<td>2021</td>
<td>42</td>
<td>1.058</td>
</tr>
</tbody>
</table>

- Total: 9,154
- Average: 1,059
Clients

For clarification, the number of clients is smaller than the number of certificate holders as 1 client can have more than 1 QMS (quality management certificate) (for example: more than 1 plant).

Moreover during this transition period, some clients have both a QMS Directive certificate and a QMS Regulation certificate.
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**Certification holders**

Legend:
dotted pattern = directives
plain pattern = regulations

Estimation of number of Certification holders under **Directives** in 2021

AIMDD + MDD
13,984
89,7%

MDR
820
5,3%

IVDD
678
4,3%

IVDR
105
0,7%

Estimation of number of Certification holders under **Regulations** in 2021


Total certification holders estimated to
14,662 / 30 NBs

Based on QMS (quality Management System) certificates
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- Clients of the NB are SMEs at more than 50%

![Pie Chart]
- Yes: 18 (60%)
- No: 12 (40%)
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❖ Staff in 2021 (full time equivalent in MD sector)

- Total: 2.278
- Average: 1.844
- Median: 729

- FTE of employee within conformity assessment activities
- FTE of employee within administrative and supporting activities
- FTE externalised contractors within conformity assessment activities
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❖ Staff (Full Time Equivalent in MD sector):
   From 2010 to 2021

<table>
<thead>
<tr>
<th>Year</th>
<th>FTE employee</th>
<th>FTE external contractors</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>310</td>
<td>770</td>
</tr>
<tr>
<td>2012</td>
<td>277</td>
<td>688</td>
</tr>
<tr>
<td>2013</td>
<td>1.291</td>
<td>1.619</td>
</tr>
<tr>
<td>2014</td>
<td>1.692</td>
<td>1.816</td>
</tr>
<tr>
<td>2015</td>
<td>2.183</td>
<td>2.605</td>
</tr>
<tr>
<td>2016</td>
<td>2.623</td>
<td>2.726</td>
</tr>
<tr>
<td>2017</td>
<td>2.876</td>
<td>2.876</td>
</tr>
<tr>
<td>2018</td>
<td>2.726</td>
<td>531</td>
</tr>
<tr>
<td>2019</td>
<td>2.726</td>
<td>583</td>
</tr>
<tr>
<td>2020</td>
<td>2.876</td>
<td>561</td>
</tr>
<tr>
<td>2021</td>
<td>4.122</td>
<td>729</td>
</tr>
</tbody>
</table>
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● Expiring Directives certificates at end of 2021

- Total: 14,063
  - IVDD: 655
  - MDD: 13,104
  - IVDD: 219
  - MDD: 3,447
  - AIMDD: 52
  - AIMDD: 304

Expiration

- IVDD: 103
- MDD: 1,580
- AIMDD: 48
Expiration 2022

- IVDD: 219
- MDD: 3,474
- AIMDD: 52
Expiration 2023

- AIMDD: 304
Expiration 2024

Estimation of capacity to issue certificates per year: 6,300
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Trends in expiring Directives certificates (comparison data 2020 and 2021)

- 31%
+ 5%
+ 25%

<table>
<thead>
<tr>
<th>Directives</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDD</td>
<td>2,021</td>
<td>1,580</td>
</tr>
<tr>
<td>AIMDD</td>
<td>58</td>
<td>48</td>
</tr>
<tr>
<td>IVDD</td>
<td>193</td>
<td>103</td>
</tr>
<tr>
<td>MDD</td>
<td>3,253</td>
<td>3,447</td>
</tr>
<tr>
<td>AIMDD</td>
<td>36</td>
<td>52</td>
</tr>
<tr>
<td>IVDD</td>
<td>240</td>
<td>219</td>
</tr>
<tr>
<td>MDD</td>
<td>9,734</td>
<td>13,104</td>
</tr>
<tr>
<td>AIMDD</td>
<td>219</td>
<td>304</td>
</tr>
</tbody>
</table>

Expiration:
- Expiration 2022
- Expiration 2023
- Expiration 2024
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❖ Certificates evolution from Directives to Regulations (including applications)

- Directives certificates increasing (thanks to new members)
- Regulation certificates increasing (> 4 times)
- Regulation applications increasing (2,5 times)

⇒ Still numerous certificates to be transfer against MDR (> 95%) and applications to be received (75%)

- Directive certificates : small increase
- Regulation certificates increasing (17 times)
- Regulation applications increasing (> 2,5 times)

⇒ Transfer against IVDR (>90%) + new certificates against IVD Regulation tremendous