

Guidance on the health institution exemption under Article 5(5) of the Regulations on medical devices and *in vitro* diagnostic medical devices.

1 Scope and target audience

Health institutions can manufacture and use medical devices in-house and thereby address, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent CE marked device available on the market. In-house medical devices are exempted from most of the provisions of Regulations (EU) 2017/745 (medical devices Regulation, MDR) and (EU) 2017/746 (*in vitro* diagnostic medical devices Regulation, IVDR) provided they adhere to the conditions laid out in Article 5(5) of both Regulations. In order to ensure the highest level of health protection, Article 5(5) sets a number of rules regarding the manufacture and use of such in-house medical devices.

The provisions in Article 5(5) are the basis for the regulatory control and overview of in-house devices. This document provides guidance on the application of some of these rules. It is written for health care professionals and researchers of health institutions wishing to continue using in-house devices or aiming to design, manufacture and use new in-house devices. In addition, this guidance document intends to foster harmonised application of Article 5(5) by the national competent authorities.

The exemption provision from Article 5(5) is applicable to health institutions within the Union only. According to Article 6(2), health institutions outside the Union that offer diagnostic or therapeutic services through distance sales to patients in the Union must use devices that comply with the MDR or IVDR, without having the possibility of applying the in-house exemption.

While most recommendations in this document pertain to both medical devices and *in vitro* diagnostic medical devices (IVDs), some are specific to IVDs, in which case this is explicitly mentioned.

2 Clarification of commonly used terms in this guidance document

- **General safety and performance requirements:** the general safety and performance requirements of the MDR and the IVDR are applicable to in-house devices and are laid down in Annex I of both Regulations.
- **Health institution:** an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health. Health institutions include hospitals as well as institutions, such as laboratories and public health institutions that support the health care system and/or address patient needs, but which do not treat or care for patients directly. The concept of health institution does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres.
- **In-house device:** a device that is manufactured only within a health institution established in the Union and that meets all conditions set in Article 5(5) of the MDR or IVDR and is used within that same health institution.

39 • **IVDR:** Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on
40 *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision
41 2010/227/EU.

42 • **MDR:** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on
43 medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC)
44 No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

45

46 **3 Guidance on terms used in Article 5(5) of the MDR and the IVDR**

47 With the exception of the relevant general safety and performance requirements set out in Annex I,
48 the requirements of the MDR and IVDR shall not apply to **devices** manufactured and used only within
49 health institutions established in the Union, provided that specific conditions are met.

50

51 **3.1 Which devices are referred to in Article 5(5)?**

52 **MDR**

53 According to Article 1(4) of the MDR: the term ‘devices’ means (1) medical devices, (2) accessories for
54 medical devices, and (3) products listed in Annex XVI.

55 (1) ‘medical device’ is defined in Article 2(1) of the MDR.

56 (2) ‘accessory for a medical device’ is defined in Article 2(2) of the MDR.

57 (3) ‘products listed in Annex XVI’ refers to the groups of products without an intended medical purpose
58 that are listed in Annex XVI of the MDR. Applicability of the MDR for these products, and therefore
59 application of Article 5(5), will be effective from the date of application of common specifications
60 for these products.

61

62 **IVDR**

63 According to Article 1(2) of the IVDR: the term ‘devices’ means (1) IVDs, and (2) accessories for IVDs.

64 (1) ‘IVD’ is defined in Article 2(2) of the IVDR.

65 (2) ‘accessory for an IVD’ is defined in Article 2(4) of the IVDR.

66

67 **General**

68 Remarks:

69 • A protocol in the form of a written procedure that is shared between health institutions, patient
70 samples and results are not considered as being devices according to the definitions above.
71 Consequently, the MDR and IVDR do not apply to these.

72 • Any product or a combination of products which meets the definition of ‘device’ must comply
73 with the MDR or IVDR, *i.e.* either be CE marked, or be manufactured in-house and thus comply

74 with Article 5(5), or be an investigational device or a device for performance study, or be a
75 custom-made device, or be exceptionally allowed a derogation from CE marking by a competent
76 authority.

- 77 • According to the second paragraph of Article 5(5), member states shall retain the right to restrict
78 the manufacture and the use of any specific type of in-house devices. Health institutions are
79 advised to contact their competent authority or consult national legislations for possible
80 restrictions in their country.

81

82 **3.2 How to understand the terms ‘manufactured and used’?**

83 A device must be **manufactured and used** within the same health institution in order for Article 5(5)
84 to apply.

85

86 3.2.1 How to understand the term ‘**manufactured**’?

87 Manufacturing a device by a health institution can include:

- 88 • manufacturing a device from raw materials or parts or components;
- 89 • combining devices or products for a medical purpose, when the devices do not bear the
90 CE marking or where the combination of devices is not in line with their original intended
91 purpose;
- 92 • significantly modifying an existing device. A significant modification is a modification made by a
93 health institution that was not intended by the manufacturer and has an impact on the
94 conformity of the product (for example, a significant change of a medical device as described in
95 the guidance document MDCG 2020-3).

96

97 3.2.2 How to understand the term ‘**used**’?

- 98 • Devices can only be defined as in-house devices when their manufacture and use is limited to
99 health institutions established in the Union. This use within health institutions can either be
100 physically or, for instance for medical device software, remotely, provided they are not made
101 available to another legal entity. The act of using an in-house manufactured device is performed
102 within the health institution when the device is used in the care or diagnosis of a patient. If,
103 during the lifecycle of the device, the device is used outside the health institution’s premises, it
104 cannot be in-house manufactured.

105

106 Examples:

- 107 • PCR master mix: a health institution orders primers based on scientific literature and
108 manufactures its own in-house master mix containing buffer, primers, dNTPs, cofactors and
109 enzymes to run PCRs on human DNA/RNA samples.

- 110 • A health institution develops in-house a medical device software that is used on site by its
111 medical staff.

112

113 Examples of devices that do not fall under in-house devices:

- 114 • Medical device applications where patients can enter medical data outside the health
115 institution.

- 116 • Orthopaedic braces that can be adapted by patients themselves outside the health institution.

- 117 • Self-tests cannot fall under Article 5(5) if used outside the health institution's premises.
118 However, an in-house manufactured self-test can be used within the health institution by lay
119 users. Also, an in-house device can be used in the health institution's laboratory for the analysis
120 of a sample that is collected by a patient himself and consecutively sent to the laboratory.

- 121 • Manufacturing a device purely for economic reasons/financial interests.

122

123 Note:

124 The MDR and IVDR do not regulate any possible off-label use of devices by healthcare practitioners.

125

126 **3.3 Legal entity**

127 In-house devices **shall not be transferred to another legal entity.**

128 Healthcare systems are organised differently in different member states. Therefore, the concept of
129 legal entity can differ. The national competent authority can clarify how legal entity is understood
130 nationally. Here are some examples:

- 131 • One hospital can be one legal entity when there is only one health institution (one organiser)
132 within the hospital.

- 133 • One hospital can accommodate several legal entities when there are different health institutions
134 (different organisers) within the same hospital. The different health institutions can have
135 different organisational numbers and different quality management systems.

- 136 • Several hospitals (a hospital network) can belong to the same legal entity when they are all part
137 of one health institution (one organiser). They share the same organisational number and quality
138 management systems even though they might be spread over different locations.

139

140 **3.4 What is an appropriate quality management system?**

141 The manufacture and use of in-house devices must occur under **appropriate quality management**
142 **systems** (QMS).

143

144 **MDR**

145 Article 10(9) of the MDR describes the minimal aspects that a QMS for manufacturing medical devices
146 should cover. This Article can be used as guidance on how to implement an appropriate QMS for
147 manufacturing in-house devices. Below are some examples of provisions of Article 10(9) that could be
148 relevant and adapted to in-house manufacturing.

- 149 • 10(9) (a) ‘compliance with conformity assessment procedures’:

150 Health care institutions must determine how the requirements of Article 5(5) will be met. A
151 declaration must be published confirming compliance with the general safety and performance
152 requirements (see Article 5(5) (e)).

- 153 • 10(9) (b) ‘identification of applicable general safety and performance requirements and
154 exploration of options to address those requirements’:

155 As the general safety and performance requirements set out in Annex I do apply to in-house
156 devices, compliance with applicable requirements must be documented.

- 157 • 10(9) (f) ‘clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF’:

158 According to 5(5) (c), (f) and (h), there is a need for proper scientific data and analysis of that
159 data to justify that the target patient group’s specific needs cannot be met in another way than
160 by manufacturing and using the health institution’s device. The experience gained from clinical
161 use of the device should be used to review the device performance.

- 162 • 10(9) (h) ‘verification of the UDI assignments...’:

163 There is no obligation to implement a UDI (unique device identification) system. However,
164 pursuant to Article 5(5) (h), the health institution shall take all necessary corrective actions.
165 Therefore, some form of a product tracking system must be established to identify the affected
166 products and involved patients. Additionally, according to 5(5) (e) (ii), health institutions shall
167 make publicly available the details necessary to identify the devices.

- 168 • 10(9) (i) ‘setting-up, implementation and maintenance of a post-market surveillance system, in
169 accordance with Article 83’:

170 According to 5(5) (h), the health institution shall review experience gained from clinical use of
171 the device and take all necessary corrective actions.

172

173 **IVDR**

174 Article 10(8) of the IVDR describes the minimal aspects that a QMS for manufacturing medical devices
175 should cover. This Article can be used as a guidance on how to implement an appropriate QMS for
176 manufacturing in-house devices. Below are some examples of provisions of Article 10(8) that could be
177 relevant and adapted to in-house manufacturing.

- 178 • 10(8) (a) ‘compliance with conformity assessment procedures’:

179 Health care institutions must determine how the requirements of Article 5.5 will be met. A
180 declaration must be published confirming compliance with the general safety and performance
181 requirements (see Article 5.5 (f)).

182 • 10(8) (b) ‘identification of applicable general safety and performance requirements and
183 exploration of options to address those requirements’:

184 As the general safety and performance requirements set out in Annex I do apply to in-house
185 devices, compliance with applicable requirements must be documented.

186 • 10(8) (f) ‘performance evaluation in accordance with Article 56 and Annex XIII, including PMPF’:

187 According to 5(5) (d), (g)* and (i), there is a need for proper scientific data and analysis of that
188 data to justify that the target patient group’s specific needs cannot be met in another way than
189 by manufacturing and using the health institution’s device. The experience gained from clinical
190 use of the device should be used to review the performance of the in-house device.

191 * applies only to class D devices unless regulated otherwise by national provisions.

192 • 10(8) (h) ‘verification of the UDI assignments...’:

193 There is no obligation to implement a UDI system. However, pursuant to Article 5(5) (i), the
194 health institution shall take all necessary corrective actions. Therefore, some form of a product
195 tracking system must be established to identify the affected products and involved patients.
196 Additionally, according to 5(5) (f) (ii), health institutions shall make publicly available the details
197 necessary to identify the devices.

198 • 10(8) (i) ‘setting-up, implementation and maintenance of a post-market surveillance system, in
199 accordance with Article 78’:

200 According to 5(5) (i), the health institution shall review experience gained from clinical use of
201 the device and take all necessary corrective actions.

202

203 Note:

204 • For in-house IVDs, the laboratory of the health institution should be in compliance with the
205 standard EN ISO 15189 (or with national provisions regarding QMS, including national provisions
206 regarding accreditation). However, as the manufacturing process of a device is not in the scope
207 of this standard, compliance with EN ISO 15189 alone does not constitute an appropriate QMS
208 for the manufacture of in-house IVDs.

209

210 **General**

211 For both medical devices and IVDs, the QMS can cover the whole health institution or parts of the
212 health institution involved in the manufacturing or modification of the device. A QMS should include
213 a process for obtaining information about equivalent CE marked devices that become available on the
214 market.

215

216 **3.5 Justification that the target patient group’s specific needs cannot be met, or cannot**
217 **be met at the appropriate level of performance, by an equivalent device available**
218 **on the market.**

219 The health institution justifies in its documentation that the **target patient group's** specific needs
220 cannot be met, or cannot be met at the appropriate level of performance by an **equivalent device**
221 available **on the market**. The health institution should consult relevant national legislation and/or
222 guidance on this point.

223

224 **Target patient group's specific needs**

225 In this context, the **target patient group** should be understood as a group of patients who have in
226 common the same disease, condition or characteristics, that could benefit from using the device.

227 The specific needs should be understood as needs for:

- 228 • a specific device with one or more of the intended purposes specified in Article 2(1) of the
229 MDR and, for IVDs, Article 2(2) of the IVDR, and;
- 230 • a specified level of performance of that device for certain performance characteristics.

231

232 **Equivalent device in the context of the justification**

233 **MDR**

234 Annex XIV.3 of the MDR describes device characteristics that should be taken into consideration for
235 the demonstration of (non-)equivalence. These characteristics are divided into technical, biological and
236 clinical aspects.

- 237 • Technical: the device is of similar design, is used under similar conditions, has similar
238 specifications and properties including physicochemical properties, uses similar deployment
239 methods, has similar principles of operation and critical performance characteristics.
- 240 • Biological: the device uses the same materials or substances in contact with the same human
241 tissues or body fluids for a similar kind and duration of contact, has similar release characteristics
242 of substances, including degradation products and leachables.
- 243 • Clinical: the device is used for the same clinical condition or purpose, including similar severity
244 and stage of disease, at the same site in the body, in a similar population, has the same kind of
245 user, has a similar relevant critical performance in view of the expected clinical effect for a
246 specific intended purpose.

247

248 Note the different usage of the terms 'similar' and 'same'.

249 The health institution should consult the 'MDCG 2020-5 guidance on Clinical Evaluation – Equivalence'
250 for further guidance on the subject.

251 Non-equivalence should be based on scientific or clinical justifications.

252

253 **IVDR**

254 The IVDR does not provide a description of equivalent devices. However, some of the equivalence
255 characteristics listed in the MDR are also applicable to IVDs (see above). Justification that the patient
256 groups specific needs cannot be met, or cannot be met at the appropriate level of performance, by an
257 equivalent device available on the market can be based on technical or clinical aspects e.g. different
258 intended purpose, different clinical conditions, different patient group, different conditions of use,
259 different principles of operation. Non-equivalence should be based on scientific or clinical
260 justifications.

261

262 **Process for producing and reviewing the justification**

263 Before manufacturing an in-house device for the first time, a health institution should examine the
264 market for the presence and availability of equivalent CE marked devices. It is appropriate to describe
265 this process in the documentation for the in-house device. The European database on medical devices,
266 EUDAMED, could serve as one of the sources of information for the identification of equivalent CE
267 marked alternatives (e.g. for higher risk class devices, a summary of safety and (clinical) performance
268 is publicly available in EUDAMED). On the basis of its findings, the health institution should justify why
269 the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of
270 performance, by an equivalent device available on the market.

271 The health institution should continue gathering information about the availability on the market and
272 performance of potentially equivalent CE-marked devices in order to keep their in-house device
273 manufacturing up-to-date with market developments. The health institution should review its
274 justification on a regular basis, in view of its findings.

275 Once the in-house device is in use, a possible subsequent availability on the market of an equivalent
276 device does not invalidate the initial justification regarding the fulfilment of the requirements set out
277 in Article 5(5) at moment of the start of the in-house manufacturing. However, in such a case the health
278 institution should review and update its justification.

279

280 **Availability on the market**

281 Market in this context should be understood as the market of CE marked devices that is accessible to
282 the health institution according to national and local rules and regulations.

283

284 **3.6 What kind of information can be requested from health institutions by competent** 285 **authorities?**

286 The health institution provides **information upon request** on the manufacture and use of in-house
287 devices to its competent authority, which shall include a justification of their manufacturing,
288 modification and use.

289 Examples of what information can be requested:

- 290 • When an in-house device is put into service:
 - 291 - Device type.
 - 292 - Intended use.
 - 293 - Target patient group.

- 294 - A justification for the lack of equivalent CE marked alternatives.
295 - Description of the manufacturing process.
296 - Description of modifications carried out.
297 - Information regarding use: procedures, used in combination with other devices (data on
298 compatibility) etc.
299 • After the device has been used routinely:
300 - All information as described above.
301 - Number of units manufactured in a certain period and a justification of the production
302 numbers.
303 - Data regarding the performance of the device: performance outcome, incidents or
304 complaints, corrective actions undertaken.

305 Note:

- 306 • Health Institutions should consult national provisions on notifying the competent
307 authority when an in-house device is put into service, modified or its use
308 discontinued.

309

310 **3.7 Public declaration.**

311 The health institution draws up a **declaration** which it shall make **publicly available**, including: (i) the
312 name and address of the manufacturing health institution, (ii) the details necessary to identify the
313 devices, and (iii) a declaration that the devices meet the general safety and performance requirements
314 set out in the IVDR or MDR and, where applicable, information on which requirements are not fully
315 met with a reasoned justification thereof.

316 Health institutions should consult possible national legislation, rules or guidance regarding the exact
317 declaration format, language requirements and the publication conditions that need to be fulfilled (e.g.
318 publication on the health institution's website and/or on a dedicated webpage from the competent
319 authority). A proposed declaration format is provided in Annex A of this guidance. Health institutions
320 should regularly review their public declaration and update it as necessary.

321

322 **3.8 Documentation requirements.**

323 For all medical devices and for class D IVDs (or any other IVD class if deemed necessary by national
324 legislation), the health institution draws up documentation that makes it possible to have an
325 understanding of the **manufacturing facility**, the **manufacturing process**, the **design** and **performance**
326 **data** of the devices, including the **intended purpose**, and that is sufficiently detailed to enable the
327 competent authority to ascertain that the general safety and performance requirements set out in
328 Annex I of the MDR and IVDR are met. Health Institutions should consult national provisions regarding
329 possible documentation requirements for class A, B and C IVDs.

330

331 The following aspects (non-exhaustive list of examples that might be applicable) should be taken into
332 account when drafting documentation for in-house devices.

- 333 • **Manufacturing facility:** description of the infrastructure, the services and the work environment
334 needed to safely manufacture the device in a way that fulfils the product requirements, listing
335 of the equipment that is essential for production etc.
- 336 • **Manufacturing process:** explanation of the manufacturing processes, including a description of
337 the raw materials, control of suppliers, final product testing etc.
- 338 • **Design:** principles of operation of the device and its mode of action, technical specifications
339 including chemical, physical and biological properties, listing of applied standards, common
340 specifications and guidelines that are essential to meet the relevant general safety and
341 performance requirements etc.
- 342 • **Performance data:** according to Annex I of the IVDR/MDR, devices shall be designed and
343 manufactured in such a way that they are suitable with regard to the performance they are
344 intended to achieve, taking account of the generally acknowledged state of the art. A description
345 of, where applicable, **the analytical and the clinical performance data** supporting the intended
346 purpose should be provided.
- 347 • **Intended purpose of the device:** specification of indications and contra-indications, the patient
348 target group or groups, information provided by an IVD device, function of an IVD device (e.g.
349 screening, monitoring, ...), what type of specimen is used by an IVD device etc.

350

351 All information should be presented in a clear, organised, readily searchable and unequivocal way. An
352 appropriate format is described in detail in Annex II of the MDR/IVDR and can be used as guidance for
353 documentation purposes. The documentation must be kept up to date.

354

355 **3.9 Vigilance, incidents and corrective actions.**

356 The health institution reviews experience gained from clinical use of the devices and takes all
357 **necessary corrective actions.**

358 Health institutions should have a documented procedure in place to collect clinical data (please be
359 aware that collecting clinical data under Article 5(5) activities does not replace clinical
360 investigations/performance studies) and to process incidents and corrective actions for in-house
361 devices. They should consult national legislation on possible requirements regarding reporting of
362 incidents and corrective actions.

363

364 **3.10 Industrial scale.**

365 The last sentence of Article 5(5) of both Regulations, states that the exemption provisions do not apply
366 to devices manufactured on an **industrial scale**. Furthermore, the recitals of the Regulations state that
367 healthcare institutions should be able to manufacture, modify and use devices in-house and thus meet,
368 on a non-industrial scale, the specific needs of a patient group that cannot be met at an appropriate
369 level of performance by an equivalent device available on the market.

370 Industrial scale is not simply defined by the number of devices manufactured, but it is also related to
371 commercial aspects. Therefore, if the manufacturing activity of an in-house device is carried out for
372 commercial purposes, it should be considered as production on an industrial scale.

373 The exemption provisions in Article 5(5) of the Regulations should only be applicable to devices that
374 are produced by the health institutions in order to meet the patient groups' specific needs, and
375 therefore, the manufacturing process should not produce more than the estimated number of
376 required devices.

377 Note:

- 378 • 'Industrial scale' is not synonymous to 'mass-produced' as defined in the IMDRF/PMD
379 WG/N49:2018 document.
 - 380 • In case of IVDs, the analysis of a large number of patient samples does not automatically render
381 an in-house IVD to a device produced on an industrial scale.
- 382

383 **Annex A**

384

385 **Public declaration regarding the manufacture and use of in-house devices by health**
386 **institutions.**

387

388 **Name of health institution:**

389 **Address:**

390

391 *-the health institution-* declares that the devices described in the accompanying table are only
392 manufactured and used in *-the health institution-* and do meet the applicable general safety and
393 performance requirements (GSPR) of the medical devices Regulation (EU 2017/745) or of the *in vitro*
394 diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case
395 applicable general safety and performance requirements are not fully met.

396

397 **Date and location:**

398 **Name, function and signature of responsible person(s):**

399

400

401 **Table of in-house devices:**

Device identification (e.g. name, description, reference number)	Device type (IVD/ MD)	Device class	Intended purpose	Applicable GSPR met? (Y/N)	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR)

402