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MID Compliance

Understanding MID Compliance in Automated Compounding

Questions & answers

Disclaimer

This document is intended as a general informational resource on the regulatory framework applicable to automatic weighing instruments in the context of automated compounding. It does not constitute legal advice, is not directed at any specific product or manufacturer, and should not be relied upon as a substitute for qualified legal or regulatory counsel. Readers are advised to verify the specific regulatory requirements applicable in their jurisdiction and to their situation.

. What is the Measuring Instruments Directive (MID)?

The Measuring Instruments Directive (2014/32/EU) is European product legislation that regulates how specific categories of measuring instruments must be designed, assessed and placed on the EU market before they may be made available to customers. The Directive applies at manufacturer level and sets harmonised requirements for predefined instrument types listed in its annexes. In the context of pharmacy compounding, an automated system that determines mass automatically, without operator intervention, and following a predetermined programme of automatic processes characteristic of the instrument, qualifies as an Automatic Weighing Instrument (AWI) under Annex MI-006. When these criteria are met, the system falls within the scope of the MID and must undergo conformity assessment by a Notified Body prior to being placed on the market. Systems that have successfully completed this conformity assessment bear the CE + M marking, indicating that the integrated weighing function has been independently assessed in accordance with European legal metrology requirements. Instruments that have not undergone this conformity assessment may still function technically, but they have not been assessed under the MID and therefore do not carry legally defined metrological status under European product law. It is important to recognise that the MID, as harmonised European legislation, regulates the placing of instruments on the market. The use of measuring instruments in legally regulated applications may additionally be governed by national metrology legislation in each EU or EEA Member State, as set out in Question 3.

2. Why is the MID relevant for pharmacists?

Because the final release of a compounded medicine is a legally accountable act under European and national medicines law. When a pharmacist authorises a preparation for patient

use, that decision confirms that the product meets its prescribed dose and quality requirements and carries professional and legal responsibility. Where gravimetric weighing forms part of the preparation, verification or release process, the reliability and traceability of the weighing method become directly relevant to that responsibility. For manual gravimetric operations, this is long established through the mandatory use of legally verified non-automatic weighing instruments (NAWI). For automated weighing, the regulatory mechanism operates at two levels.

At EU level, the Measuring Instruments Directive places the obligation to ensure metrological conformity on the manufacturer, who may only place compliant automatic weighing instruments on the market following conformity assessment under Annex MI-006. The regulatory framework assumes that automatic weighing instruments available on the market have already undergone this assessment.

At national level, the situation may differ materially. As set out in Question 3, a significant number of EU and EEA Member States have enacted national metrology legislation that imposes obligations on the user of measuring instruments in legally regulated applications, in many cases expressly including healthcare and pharmaceutical preparation. In those jurisdictions, the pharmacist may be subject to a direct legal obligation to use only duly assessed and verified measuring instruments.

From a governance and professional accountability perspective, where a pharmacist relies on gravimetric data generated by an automated system that has not been assessed under the MID, the pharmacist should be able to justify why that data is nevertheless considered suitable for release decisions. In practice, MID-certified systems provide a substantially stronger and more defensible basis for release, because their metrological performance has been independently assessed and their accuracy limits are legally defined. Systems that have not been assessed under the MID may still produce technically accurate results, but they lack legally recognised metrological status and place the full evidentiary burden on the user during audits, inspections or incident investigations.

3. Are there national obligations for users of automatic weighing instruments?

Yes. While the MID itself primarily regulates manufacturers and the placing of instruments on the market, the use of measuring instruments in legally regulated applications is governed by national metrology legislation in each EU or EEA Member State. Harmonised EU product legislation addresses placing on the market; Member States retain competence to regulate the putting into service and use of instruments within their territory.

In practice, the majority of EU and EEA Member States have enacted national metrology laws that impose explicit obligations on users of measuring instruments, including automatic weighing instruments. In a significant number of these countries, healthcare and in some cases pharmaceutical preparation specifically, is expressly identified as a regulated application domain. In those jurisdictions, the pharmacist may be subject to a direct, legally enforceable obligation to use only duly assessed and verified measuring instruments.

Institutions and pharmacists are therefore advised not to assume that MID compliance is exclusively a manufacturer concern. They should verify the specific regulatory position in their own jurisdiction, including whether healthcare or pharmaceutical preparation falls within the

scope of nationally regulated measurement tasks.

4. What does "CE + M" mean under the MID?

Under the MID, instruments that have completed the required conformity assessment must bear two distinct markings, each with its own legal basis:

- the CE marking, indicating conformity with all applicable EU product legislation under which the instrument falls; and
- the supplementary metrology marking, consisting of the capital letter M and the last two digits of the year in which the marking was affixed, enclosed within a rectangle. This marking is specific to the MID and indicates conformity with the metrological requirements of the Directive.

In addition, the marking includes the four-digit identification number of the Notified Body responsible for the conformity assessment.

In professional and regulatory practice, the simplified term "CE + M" is commonly used to refer to MID-certified measuring instruments. However, only the complete marking including the Notified Body number and year, demonstrates that the instrument has undergone third-party conformity assessment under the MID.

This approach is consistent with NAWI, which are likewise required to display legally prescribed metrological markings to demonstrate verification and conformity for their intended use.

In addition to the CE + M marking, every MID-certified weighing instrument must display its metrological parameters, such as maximum and minimum capacity (Max/Min), accuracy class, and the applicable e- and d-values. These parameters define the exact conditions under which the conformity assessment is valid.

5. Where can I find these markings?

All mandatory MID markings and metrological parameters must be displayed on the type plate of the weighing instrument. This type plate is affixed to the weighing module or to the integrated measuring unit that performs the weighing function.

Depending on the system design, the same information may also be reproduced in software information screens or in the technical documentation. In principle, the legally relevant marking is the one physically affixed to the instrument.

On a MID-certified automatic weighing instrument, the type plate will typically show, for example:

CE M 0122 25 Max = 1500 g Min = 0 g e = 0.2 g d = 0.02 g Accuracy class: Y(II)

This combination of markings confirms both that the instrument has undergone conformity assessment under the MID by a Notified Body, and the specific metrological parameters under which that certification is valid.

A comparable principle applies to NAWI, which must also display legally prescribed verification and metrological markings. In both cases, the absence of such marking indicates that the weighing function has not been assessed under the applicable legal metrology framework.

6. Isn't a CE mark enough?

No. A standard CE mark issued under directives such as the Machinery Directive (2006/42/EC)

confirms compliance with essential requirements for mechanical, electrical and functional safety. It does not assess or guarantee the metrological performance of a system, such as weighing accuracy, repeatability or traceability.
Where a system performs automatic weighing, these metrological aspects fall within the scope of the Measuring Instruments Directive. Only systems that have undergone the applicable MID conformity assessment and bear the CE + M marking have had their weighing function independently evaluated under European legal metrology.
Where multiple EU directives apply to the same product, the manufacturer must comply with all applicable directives before placing the product on the market. The CE marking then covers conformity with all applicable legislation, but the supplementary metrology marking (M) is specific to the metrological requirements of the MID.
A system bearing only a standard CE mark may be safe to operate, but its weighing results have not been assessed under the MID and therefore do not carry legally defined metrological status under EU product law.

7. We validated our system internally (IQ/OQ/PQ). Isn't that enough?

No. Internal qualification and validation (IQ/OQ/PQ) demonstrate that a system performs consistently and as intended within a specific operational environment. They confirm technical reliability and process control, but they do not constitute assessment under European legal metrology. These two frameworks have different legal foundations and serve different purposes. Validation derives from Good Manufacturing Practice (GMP) requirements and is the responsibility of the user. MID conformity assessment derives from EU product legislation and is the responsibility of the manufacturer. Validation asks whether a system works reliably in practice; MID conformity assessment asks whether an automatic weighing instrument meets predefined legal metrology requirements, including accuracy limits and defined operating conditions, as verified by an independent Notified Body. They are complementary, not interchangeable. A system may therefore be fully validated from a GMP perspective and still not have been assessed under the Measuring Instruments Directive. In such cases, the weighing results may be technically sound, but they lack legally defined metrological status under the MID and must be justified entirely through local validation and documentation.
In practice, this means that internal validation cannot replace MID conformity assessment for automatic weighing functions. Where weighing data plays a role in verification or release decisions, the absence of MID assessment significantly increases the evidentiary and justification burden for the user.

8. What happens if a system is not MID-certified?

Under the MID, the responsibility for ensuring that automatic weighing instruments undergo the required conformity assessment before they are placed on the EU market rests with the manufacturer. A system that performs automatic weighing but has not undergone conformity assessment under the Measuring Instruments Directive has not been assessed under European legal metrology. This does not automatically prohibit its use by healthcare institutions, but it does have important practical and regulatory implications. For the user, the practical consequences of the absence of MID assessment include:

- the weighing function has no legally defined metrological status under the MID;
- accuracy limits, permissible errors and operating conditions are not independently verified under legal metrology;
- all justification for the suitability of the weighing data rests entirely on local validation, documentation and risk assessment;
- in jurisdictions where national metrology legislation imposes user obligations for regulated measurement tasks (see Question 2a), additional questions may arise under national law.

During inspections or audits, the absence of MID assessment may raise questions about the adequacy of gravimetric control, particularly where weighing results are used for preparation verification or release decisions. This becomes especially relevant when questions are raised about the preparation itself, for example following a dosing deviation, adverse event or quality complaint. In such situations, the focus typically shifts from system functionality to evidentiary questions: how was the dose verified, what accuracy limits applied, and how can it be demonstrated that the intended quantity was actually prepared. Where no MID assessment is available, there is no independent metrological reference to rely on. The user must reconstruct and defend the gravimetric part of the preparation process solely on the basis of internal records and validation data. This does not in itself imply fault or non-compliance by the user, but it significantly complicates the defence of the preparation in incident investigations and may increase the likelihood of findings, corrective actions or imposed restrictions if the justification is considered insufficient.

9. My balances are certified (for example OIML or NAWI). Doesn't that make the system compliant?

Not necessarily. Certification or verification of individual balances does not automatically make an automated compounding system compliant with the Measuring Instruments Directive (MID 2014/32/EU). Once a balance is integrated into a system that performs automatic weighing as part of dosing, mixing, verification or recording, the entire system becomes a new measuring instrument in legal metrology terms. At that point, metrological performance is no longer determined by the balance alone, but by the interaction between hardware, control software, pumps, actuators and data handling. As a result, component certification does not substitute for system-level conformity assessment. Even if a balance is individually certified under OIML or verified as a NAWI, this certification applies only to the balance as a standalone instrument, not to the integrated automated system. For automatic weighing instruments, the MID requires that the complete system undergo conformity assessment by a Notified Body under Annex MI-006. Only the assessed integrated system may bear the CE + M marking and be accompanied by an EU Declaration of Conformity referencing Directive 2014/32/EU. In practice, this means that:

- a pharmacy cannot rely on the balance's certificate alone to claim MID conformity of the system;
- the manufacturer must demonstrate that the integrated weighing function, including software and data handling, meets MID requirements;
- without system-level assessment, the weighing results lack legally defined metrological status under the MID, even if the underlying balance is technically precise.

In short, a certified balance inside a non-MID-assessed automated system may measure accurately, but it does not provide the same level of legal metrological assurance as a fully assessed automatic weighing instrument. Only system-level MID conformity assessment establishes a clear, independently verified basis for traceability and defensibility.

10. What should institutions and decision makers do, and what if internal balances are already certified (e.g. OIML or NAWI)?

Institutions and decision makers should first recognise that certification or verification of individual weighing modules does not make an integrated automated compounding system compliant with the Measuring Instruments Directive. Once a balance is integrated into an automated system that performs weighing as part of dosing, mixing, verification or data recording, the system as a whole constitutes a new measuring instrument in legal metrology terms. Institutions and decision makers are therefore advised to:

- explicitly require MID conformity of the integrated system, not only certification of individual balances, in procurement specifications, tender requirements and contractual commitments;
- verify that the manufacturer's documentation includes the CE + M marking, Notified Body number, and year on the type plate of the instrument;
- request the EU Declaration of Conformity (DoC), the legally required document in which the manufacturer declares conformity with Directive 2014/32/EU and identifies the Notified Body from the manufacturer;
- verify the applicable national metrology legislation in their own jurisdiction, including whether user obligations apply for automatic weighing instruments in healthcare or pharmaceutical applications (see Question 2a);
- avoid relying solely on statements such as "OIML-approved balance" or "NAWI-certified scale" as proxies for system-level legal metrology compliance.

Taking this approach aligns procurement and governance decisions with the regulatory logic applied to both manual (NAWI) and automatic (AWI) weighing and substantially reduces downstream justification and evidentiary risk.

11. Why does this matter so much for pharmacists and QA managers?

Because gravimetric weighing forms a critical link in the chain of responsibility for medicine preparation. Where weighing results are used to verify dose accuracy or support release decisions, those results must be defensible, not only at the time of preparation, but also retrospectively. If a dose deviation, quality incident or adverse event occurs and the automated weighing system has not been assessed under the Measuring Instruments Directive, the focus of review typically shifts from system functionality to evidentiary questions. These include how the dose was verified, which accuracy limits applied, and how it can be demonstrated that the intended quantity was actually prepared. In the absence of MID assessment, there is no independent, legally defined metrological reference for the weighing function. As a result, pharmacists and QA managers must rely entirely on internal validation data, records and procedural controls to reconstruct and defend the gravimetric aspects of the preparation process.

This does not imply fault or non-compliance by itself. However, it significantly increases the burden of proof on the user and reduces the ability to rely on external, third-party assessed metrological standards during audits, inspections or incident investigations.

12. What does true compliance look like?

A compliant automated compounding system is one that has been placed on the EU market in accordance with all applicable product legislation, including the Measuring Instruments Directive where automatic weighing is performed. For systems falling within the scope of the MID, true compliance is demonstrated by the following elements taken together.

On the instrument itself, the presence of a complete and correct type plate showing:

- the CE marking, confirming conformity with applicable EU product legislation;
- the supplementary metrology marking (M followed by the last two digits of the year), confirming conformity with the metrological requirements of the MID;
- the four-digit Notified Body number;
- and the applicable metrological parameters (such as Max/Min capacity, accuracy class, and e- and d-values).

In the accompanying documentation, the availability of:

- an EU Declaration of Conformity (DoC) issued by the manufacturer, explicitly referencing Directive 2014/32/EU and identifying the Notified Body. A system for which no Declaration of Conformity is available is not fully compliant, even if the type plate markings are present;
- instructions and information accompanying the instrument as required by the MID.

Together, these elements demonstrate that the integrated weighing function has been independently assessed at system level under European legal metrology, within clearly defined operating limits.

13. What are the risks for pharmacies using non-MID systems?

The risks associated with relying on automated weighing systems that have not been assessed under the Measuring Instruments Directive are primarily practical, evidentiary and governance-related, rather than immediate prohibitions and typically include:

Regulatory and quality risk: During inspections or audits, the absence of MID assessment may lead to increased scrutiny of gravimetric controls. This can result in findings, GMP observations or requests for corrective actions where the adequacy of weighing accuracy and verification cannot be sufficiently demonstrated.

Evidentiary risk: If a dosing deviation, quality incident or adverse event occurs, weighing data generated by a non-MID-assessed system lacks an independent, legally defined metrological reference. This can significantly complicate the ability to demonstrate retrospectively that the correct quantity was prepared.

Professional accountability risk: Pharmacists and QA managers remain professionally responsible for release decisions and the qualification of critical equipment. Where reliance is placed on a weighing function that has not been independently assessed under legal metrology, the burden of justification rests entirely with the user.

National regulatory risk: In jurisdictions where national metrology legislation imposes user obligations for regulated measurement tasks including, in many countries, healthcare and pharmaceutical preparation (see Question 3), the use of a non-assessed automatic weighing instrument may raise questions under national law.
Operational and financial risk: Increased validation requirements, additional investigations, requalification activities, temporary process restrictions or eventual system replacement may result in downtime and unplanned costs.

In summary, use of a non-MID-assessed automated weighing system is not automatically prohibited in all circumstances. However, when issues arise, the pharmacy must be able to fully justify its reliance on the system without the support of third-party metrological assessment, which materially increases regulatory, evidentiary and operational risk.

14. What if we were not aware of the requirement?

Lack of awareness does not in itself create non-compliance for healthcare institutions or pharmacists, as the Measuring Instruments Directive primarily regulates manufacturers and the placing of products on the market.
However, awareness matters from a governance and accountability perspective. Once an institution becomes aware that an automated system performs automatic weighing and has not been assessed under the MID, continued reliance on that system can no longer reasonably be justified solely on the basis of misunderstanding or prevailing market practice.
From that point onward, inspectors and auditors are likely to expect that the institution:

- has formally assessed the regulatory status of the system, including under applicable national metrology legislation;
- has documented its risk assessment and justification for continued use, if any;
- and has taken reasonable steps to address the situation in future procurement or system selection decisions.

Continued use of a non-MID-assessed system following awareness is not automatically illegal for the user, but it represents a conscious acceptance of regulatory and evidentiary risk. In inspections or incident investigations, the absence of documented justification and mitigation measures may weigh more heavily once the issue has been identified.

15. What if the purchase was made with EU or public funding?

Publicly funded procurement programmes such as EU structural funds, recovery instruments or national healthcare subsidies, typically require that procured equipment complies with all applicable EU product legislation at the time it is placed on the market and put into service. Where an automated compounding system performs automatic weighing that falls within the scope of the Measuring Instruments Directive, this may include conformity with the MID at manufacturer level. If such conformity has not been established, auditors reviewing the procurement may examine whether the applicable regulatory requirements were identified and verified during the procurement process. The actual consequences depend on the specific terms and conditions of the funding programme and the nature of the audit findings. In practice, procurement decisions benefit from clear verification of all applicable EU product

legislation, including the MID where relevant, to avoid ambiguity during subsequent funding reviews.

16. What about tenders without EU funding?

Even where tenders are privately funded and not linked to EU or public subsidy schemes, compliance with applicable EU product legislation remains relevant, particularly at the level of procurement requirements and contractual commitments. Where an automated compounding system performs automatic weighing that falls within the scope of the Measuring Instruments Directive, MID conformity applies at manufacturer level. In many tenders, this is reflected indirectly through contractual clauses requiring compliance with "all applicable EU legislation" or equivalent regulatory standards. In this context, clear compliance with all applicable EU product legislation, including the MID where relevant, reduces ambiguity, limits downstream disputes and protects both contracting parties by establishing a defensible regulatory baseline.

Executive summary for decision makers

The Measuring Instruments Directive (MID, 2014/32/EU) establishes the regulatory framework for automatic weighing instruments placed on the EU market. Where gravimetric weighing is an integral part of automated compounding, MID conformity provides the only independently assessed and legally defined metrological reference for the weighing function.

The primary obligation under the MID rests on the manufacturer, who must ensure that automatic weighing instruments undergo the required conformity assessment before they are placed on the market. In addition, the majority of EU and EEA Member States have enacted national metrology legislation that imposes obligations on the user of measuring instruments in legally regulated applications. In a significant number of these countries, healthcare and pharmaceutical preparation are expressly identified as regulated domains. Institutions are advised to verify the applicable national regulatory position.

While internal validation and procedural controls remain essential from a GMP perspective, they do not replace legal metrology assessment. These two frameworks have different legal foundations. GMP validation derives from pharmaceutical regulation and is the user's responsibility. MID conformity derives from EU product legislation and is the manufacturer's responsibility. They are complementary, not interchangeable.

In the absence of MID conformity, reliance on gravimetric data is based entirely on local validation and documentation, which significantly increases the evidentiary and justification burden during audits, inspections or incident investigations.

For decision makers responsible for patient safety, regulatory compliance and institutional accountability, MID-compliant automated weighing equipment accompanied by a valid EU Declaration of Conformity referencing Directive 2014/32/EU represents the most robust and defensible baseline for gravimetric preparation within automated compounding processes.