The Compounding Company
Making parenteral medication safer.

MID Compliance

# Understanding MID Compliance in Automated Compounding

**Questions & answers**

## 1. 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 according to a predefined procedure, 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 without this marking 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.

## 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 is different. Under the Measuring Instruments Directive (MID), the obligation to ensure metrological conformity is placed primarily on the manufacturer, who may only place compliant automatic weighing instruments (AWI) on the market following conformity assessment under Annex MI-006. As a result, the MID does not generally impose a direct legal obligation on pharmacists to use MID-certified automatic weighing systems. However, the regulatory framework assumes that automatic weighing instruments placed on the market are already compliant. Where a pharmacist relies on gravimetric data generated by an

automated system that has not been assessed under the MID, the pharmacist must fully 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. Non-MID systems 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. What does "CE + M" mean under the MID?

The CE + M marking indicates that a weighing instrument has undergone conformity assessment under the Measuring Instruments Directive (MID) and complies with the applicable legal metrology requirements at the time it was placed on the EU market. For automatic weighing instruments, the CE + M marking confirms that the integrated weighing function has been independently assessed by a Notified Body in accordance with the relevant annex of the MID (for automated systems typically Annex MI-006). This assessment covers the instrument's metrological performance, including accuracy, repeatability and defined operating conditions.
In its complete legal form, the MID marking consists of:

- CE - indicating conformity with applicable EU product legislation;
- M - indicating conformity with the metrological requirements of the MID;
- A four-digit Notified Body number - identifying the Notified Body responsible for the conformity assessment (e.g. 0122 for NMi Certin B.V.);
- The last two digits of the year in which the marking was affixed.

In professional and regulatory practice, the simplified term "CE + M" is commonly used to refer to MID-certified weighing instruments. However, only the full 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 non-automatic weighing instruments (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.

## 4. 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. However, the legally relevant marking is the one physically affixed to the instrument itself. On a MID-certified automatic weighing instrument, the type plate will typically show, for example:

CE M xxxx 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 (CE + M + Notified Body number + year), and
- the specific metrological parameters under which that certification is valid.

A comparable principle applies to non-automatic weighing instruments (NAWI), which must also display legally prescribed verification and metrological markings. In both cases, the physical marking on the instrument itself is decisive; the absence of such marking indicates that the weighing function has not been assessed under the applicable legal metrology framework.

## 5. 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 (MID). Only systems that have undergone the applicable MID conformity assessment and bear the CE + M marking, affixed following assessment by a Notified Body, have had their weighing function independently evaluated under European legal metrology. A system bearing only a standard CE mark may be safe to operate, but it's weighing results have not been assessed under the MID and therefore do not carry legally defined metrological status under EU product law. This distinction mirrors the long-established situation for manual weighing, where non-automatic weighing instruments (NAWI) used for legally relevant purposes are subject to mandatory legal metrology requirements.

## 6. 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. Validation answers the question whether a system works reliably in practice. MID conformity assessment addresses a different question: whether an automatic weighing instrument meets predefined legal metrology requirements, including accuracy limits and defined operating conditions, as verified by an independent Notified Body. 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.

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

A system that performs automatic weighing but has not undergone conformity assessment under the Measuring Instruments Directive (MID) 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. In such cases:

- 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.

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. As a result, 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 imply fault or non-compliance by itself, 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.

## 8. 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 a 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.

## 9. 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 (for example OIML- or NAWI-certified balances) does not make an integrated automated compounding system compliant with the Measuring Instruments Directive (MID). 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. In that situation, metrological performance is determined not only by the balance itself, but by the interaction between hardware, control software and data handling. Even where internal balances are individually certified:

- the integrated weighing function, including software control and data processing, must be assessed as part of a system-level conformity assessment by a Notified Body;
- only the assessed integrated system may bear the CE + M marking and be accompanied by a Declaration of Conformity referencing Directive 2014/32/EU.

Without such system-level assessment, the automated weighing function has not been assessed under the MID, regardless of the certification status of individual components. In practice, this means that reliance on certified internal balances alone does not provide a legally defined metrological reference for the integrated weighing process. Institutions and decision makers are therefore advised to:

- explicitly require MID conformity of the integrated system, not only certification of individual balances;
- verify that the manufacturer's documentation for the system as placed on the market
- includes the CE + M marking, Notified Body number and year;

- 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.

## 10. 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.

## 11. 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 presence of a complete and correct type plate showing:

- the CE marking, confirming conformity with applicable EU product legislation for safety and performance;
- the M marking, confirming conformity with the metrological requirements of the MID;
- the four-digit Notified Body number, identifying the Notified Body that carried out the conformity assessment;
- the last two digits of the year in which the marking was affixed;
- and the applicable metrological parameters (such as Max/Min capacity, accuracy class, and e- and d-values).

Together, these markings demonstrate that the integrated weighing function has been independently assessed at system level under European legal metrology, within clearly defined operating limits. Such compliance does not merely indicate that the equipment is safe to

operate, but that its weighing performance is independently verified, legally defined and externally defensible during audits, inspections and incident or patient-safety reviews.

## 12. 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. These risks 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 and legal 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.
- **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. 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.

## 13. 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. In most EU Member States, there is no general legal obligation for users to operate only MID-certified automatic weighing instruments. However, awareness does matter 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 be justified on the basis of misunderstanding or prevailing market practice alone. From that point onward, inspectors and auditors are likely to expect that the institution:

- has formally assessed the regulatory status of the system;
- 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 after awareness is therefore not automatically illegal, 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.

## 14. 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 (f.e. COVID-19 recovery grants)—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 includes conformity with the MID at manufacturer level. If such a system has not undergone MID conformity assessment, its weighing function has not been assessed under applicable EU legal metrology, even if the equipment is otherwise safe and operational. In the context of audits or funding reviews, this may raise questions about whether the procurement fully met the eligibility and compliance conditions attached to the funding. Auditors may then examine:

- whether the applicable regulatory requirements were identified during procurement;
- whether compliance was verified prior to purchase;
- and whether reliance was placed on incomplete or incorrect conformity claims.

Depending on the funding scheme and audit findings, this can result in requests for clarification, corrective measures or, in some cases, partial or full recovery of the granted funds. In practice, procurement of non-MID-assessed automated weighing systems does not automatically invalidate public funding. However, once identified, it can introduce a material compliance risk that transforms a subsidy from a benefit into a potential financial exposure.

## 15. 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. If a system supplied under such a tender has not been assessed under the MID where this would be applicable, this may give rise to several practical risks:

- questions regarding whether the procurement requirements were correctly met;
- potential contractual disputes if regulatory conformity was explicitly or implicitly warranted;
- reputational risk for both purchaser and supplier if non-conformity becomes apparent during audits, inspections or incident reviews;

- increased scrutiny in future tender evaluations, particularly where regulatory compliance forms part of the selection or exclusion criteria.

In this context, MID conformity does not function primarily as a usage prohibition, but as a risk-allocation and assurance mechanism. Clear compliance with applicable EU product legislation 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) 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. While internal validation and procedural controls remain essential, they do not replace legal metrology assessment. 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. From a governance perspective, use of non-MID-assessed automated weighing systems can introduce material regulatory, contractual and financial risk, particularly in publicly funded projects or regulated procurement environments. It also places greater professional accountability on pharmacists and QA managers when gravimetric decisions must be defended retrospectively. For decision makers responsible for patient safety, regulatory compliance and institutional accountability, MID-compliant automated weighing equipment represents the most robust and defensible baseline for gravimetric preparation within automated compounding processes.