



Performance,
Quality &
Safety



World Health
Organization

WHO IMD-PQS Annual Review 2025

PRODUCT RESELLER - FORM A

(COMPANY REVIEW FORM)

SECTION 1a. CHAIN OF CUSTODY

MANDATORY

Original product manufacturer company name:

Reseller company name (current applicant / PQ Holder):

SECTION 1b. RESELLER DETAILS

MANDATORY

Registered Company Name:

License Issuing Country:

Manufacturing site postal address:

Road name & number:

Complement:

Postal code:

City:

Country:

Manufacturing site web address:

Manufacturing site contact number

Country code:

Area code:

Telephone:

Contact person 1 name:

Contact person email address:

@

Contact person name contact number:

Country code:

Area code:

Telephone:

Contact person 2 name:

Contact person email address:

@

Contact person name contact number

Country code:

Area code:

Telephone:

CONTINUES ON NEXT PAGE →



Performance,
Quality &
Safety



World Health
Organization

SECTION 1c. PRODUCT MANUFACTURER DETAILS

MANDATORY

!! USE THIS SECTION TO PROVIDE INFORMATION ABOUT THE ORIGINAL PRODUCT MANUFACTURER !!

| |
|--|
| Registered Company Name (MANUFACTURER): |
| License Issuing Country: |
| Manufacturing site postal address: Road name & number: Complement: Postal code: City: Country: |
| Manufacturing site web address: |
| Manufacturing site contact number Country code: Area code: Telephone: |
| Contact person 1 name: |
| Contact person email address: @ |
| Contact person name contact number: Country code: Area code: Telephone: |
| Contact person 2 name: |
| Contact person email address: @ |
| Contact person name contact number Country code: Area code: Telephone: |

SECTION 2a. RESELLER LICENCES

MANDATORY

INSTRUCTIONS:

Complete the information in Table 2a. below.

One (1) certified copy (.pdf) of each licence must also be submitted.

Translations - Any original document in languages other than English must be accompanied by an official notarized English translation.

Resellers that do not provide valid licences will not be considered.

The submission of invalid licenses will result in the automatic suspension of all manufacturer products until valid licenses are provided.

CONTINUES ON NEXT PAGE →



Table 2a. – Mandatory Licencing

| | Formal document no. | Issue date (DD-MMM-YY) | Expiry date (DD-MMM-YY) |
|--|---------------------|------------------------|-------------------------|
| MANDATORY: Company license or Registration document | | | |
| Optional: Manufacturing license | | | |
| Optional: Other:..... | | | |

SECTION 2b. ORIGINAL MANUFACTURER LICENCES

MANDATORY

!! USE THIS SECTION TO PROVIDE INFORMATION ABOUT THE ORIGINAL PRODUCT MANUFACTURER !!

INSTRUCTIONS:

Complete the information in Table 2b. below.

One (1) certified copy (.pdf) of each licence must also be submitted.

Translations - Any original document in languages other than English must be accompanied by an official notarized English translation.

Resellers that do not provide valid manufacturer licences will not be considered.

The submission of invalid licenses will result in the automatic suspension of all of the resellers products until valid licenses are provided.

Table 2b. – Mandatory **MANUFACTURER** Licencing

| | Formal document no. | Issue date (DD-MMM-YY) | Expiry date (DD-MMM-YY) |
|--|---------------------|------------------------|-------------------------|
| MANDATORY: Company license or Registration document | | | |
| Optional: Manufacturing license | | | |
| Optional: Other:..... | | | |

CONTINUES ON NEXT PAGE →



Performance,
Quality &
Safety



World Health
Organization

SECTION 3a. RESELLER CERTIFICATES

MANDATORY

INSTRUCTIONS: Complete the information in Table 3a. below.

One (1) certified copy (.pdf) of each certificate is required.

Translations - Any original document in languages other than English must be accompanied by an official notarized English translation.

Resellers that do not provide valid certificates will not be considered.
Email confirmation of a pending certificate validation will not be accepted.

The submission of invalid certificates will result in automatic suspension of all manufacturer products until valid certificates are provided.

A website link to a certification authentication page is mandatory for certification verification. **PLEASE VERIFY THAT WEBLINK FUNCTIONS.**

All certification bodies should be ILAC accredited.

Certificates expiring within three months of the Annual Review (i.e. between April to June 2025) must be accompanied by a copy of a renewal request letter.

Table 3a. – Mandatory Certification

| Requirements per IMD-PQS category | Certificate | Certificate accreditation year (e.g. 2015) | Certification authority (certified by) | Website link for certification verification <i>MANDATORY</i> | Expiry date (DD-MMM-YY) |
|--|-----------------|--|--|---|-------------------------|
| ALL CATEGORIES Except E008 & E013 | ISO 9001:2015* | | | | |
| E001 E003 E004 | ISO 14001:2015* | | | | |
| E008 E013 | ISO 13485:2016* | | | | |
| Optional | 93/42/EEC | | | | |
| Other approval marks (e.g. CE, UL, FDA or EMA): | | | | | |



SECTION 3b. ORIGINAL MANUFACTURER CERTIFICATES

MANDATORY

!! USE THIS SECTION TO PROVIDE INFORMATION ABOUT THE ORIGINAL PRODUCT MANUFACTURER !!

INSTRUCTIONS:

Complete the information in Table 3b. below.

One (1) certified copy (.pdf) of each certificate is required.

Translations - Any original document in languages other than English must be accompanied by an official notarized English translation.

Resellers that do not provide valid manufacturer certificates will not be considered. Email confirmation of a pending certificate validation will not be accepted.

The submission of invalid certificates will result in automatic suspension of all manufacturer products until valid certificates are provided.

A website link to a certification authentication page is **mandatory for certification verification. PLEASE VERIFY THAT WEBLINK FUNCTIONS.**

All certification bodies should be ILAC accredited.

Certificates expiring within three months of the Annual Review (i.e. between April to June 2025) must be accompanied by a copy of a renewal request letter.

Table 3b. – Mandatory **MANUFACTURER** Certification

| Requirements per IMD-PQS category | Certificate | Certificate accreditation year (e.g. 2015) | Certification authority (certified by) | Website link for certification verification MANDATORY | Expiry date (DD-MMM-YY) |
|--|-----------------|--|--|---|-------------------------|
| ALL CATEGORIES Except E008 & E013 | ISO 9001:2015* | | | | |
| E001 E003 E004 | ISO 14001:2015* | | | | |
| E008 E013 | ISO 13485:2016* | | | | |
| Optional | 93/42/EEC | | | | |
| Other approval marks (e.g. CE, UL, FDA or EMA): | | | | | |



Performance,
Quality &
Safety



World Health
Organization

SECTION 4. CHANGES TO MANUFACTURING INFORMATION

MANDATORY

INSTRUCTIONS:

If no manufacturing changes have occurred, or are expected to occur, between April 2024 and March 2025, please tick **NO**.

If changes **HAVE** occurred, resellers must submit documentation verifying the amended information.

Table 4 – Changes to manufacturing information

| | | <i>Please provide details of changes:</i> |
|--|---|---|
| Are there any changes to the manufacturer's company name and/or status ? | YES <input type="checkbox"/> NO <input type="checkbox"/> | |
| Are there any changes to the manufacturing site ? | YES <input type="checkbox"/> NO <input type="checkbox"/> | |