Performance, Quality & Safety

World Health Organization

WHO IMD-PQS Annual Review 2024

PRODUCT MANUFACTURER - FORM A

(COMPANY REVIEW FORM)

SECTION 1. MANUFACTURER 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:

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SECTION 2. MANUFACTURER LICENCES — MANDATORY

INSTRUCTIONS: Complete the information in Table 2 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.

Manufacturers 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.

Table 2 – 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 3. MANUFACTURER CERTIFICATES — MANDATORY

INSTRUCTIONS: Complete the information in Table 2 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.

Manufacturers 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 the 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 VERFIY THAT WEBLINK FUNCTIONS.**

All certification bodies should be ILAC accredited.

Certificates expiring between April of the 2024 and March 2025: kindly provide documentation demonstrating the **intention and plan to renew.**

Table 3 – Mandatory 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):					

SECTION 4. CHANGES TO MANUFACTURING INFORMATION MANDATORY

INSTRUCTIONS: If no changes have occurred, or are expected to occur, between last April, and current March please tick **NO**.

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

Table 4 – Changes to manufacturing information

		Please provide details of changes:
Are there any changes to the **company name** and/or **status**?	YES ☐ NO ☐	
Are there any changes to the **manufacturing site**?	YES ☐ NO ☐	