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World Health Organization

WHO IMD-PQS Annual Review 2024

PRODUCT MANUFACTURER OR RESELLER - FORM B

(PRODUCT REVIEW FORM)

Important: **In order to facilitate supply security and risk analyses, applicants are required to provide the volume of units sold and highest price per unit.**

****All information provided by applicants will be treated in the strictest confidence****

SECTION 1. APPLICANT IDENTIFICATION — MANDATORY

Applicant Company Name:	

SECTION 2. APPLICANT REQUEST ANNUAL REVIEW 2024 — MANDATORY

IMD-PQS code :	E 0 _ _ / _ _ _
Action requested Annual Review 2024:	☐ **Withdraw** product from the IMD-PQS Catalogue ☐ **Renew** product´s prequalified status

SECTION 3. PRODUCT DETAILS — MANDATORY

Table 3 – Product details

Product "Description" as written on Product Sheet	
Product "Manufacturers' reference" as written on Product Sheet	
SALES: Number of pieces sold in last 12 months (*total turnover sold to any organization)	(Pieces)
FAILURES: Total number of pieces affected by a failure or failure complaint	(Pieces)

SECTION 4. PRICE DETAILS MANDATORY

INSTRUCTIONS: Resellers/manufacturers of all devices ***except*** RTMDs complete Table 4.a.

Resellers/manufacturers of RTMDs complete Table 4b.

4.a. PRICE DETAILS – ALL DEVICES EXCEPT RTMDs

INSTRUCTIONS: Multiple volume pricing buckets will no longer be displayed in the IMD-PQS equipment catalogue. **Only one indicative price will be displayed**, and must be provided by the manufacturer based on the following criteria:

- **Highest price per unit** based on a representative order of 100 units
- Pricing **inclusive of all IMD-PQS required accessories**, i.e., voltage stabilizers (mains only), base offering of temperature monitoring device (e.g. 30DTR)
- Currency: **USD or EUR only**
- Incoterms: **Ex-Works** (EXW) only; excl. VAT
- **Packaging based on IMD-PQS specification requirements**

Table 4a. – Price details **(all devices *except* RTMDs)**

	Price	Currency (USD or EUR)
Highest unit price (Ex-works) MANDATORY		

4.b. PRICE DETAILS – RTMDs ONLY

INSTRUCTIONS: Manufacturers/resellers of RTMDS must complete a pricing table based on different **product and service purchase options**. This is required in order to capture and communicate comparable, indicative pricing across products and services.

Because pricing for services, particularly communication costs (e.g. global SIM cards) can vary significantly across geographies, a median price must be provided for each contract option. This pricing matrix must be provided in Table 4b based on the following criteria:

- **Price per purchase option**: 1-year contract price per unit
- Product **hardware purchase price** per unit (base unit, one temperature sensor with standard lead length, one door open sensor, solar charging kit, etc.)
- Currency: **USD or EUR only**
- Incoterms: **Ex-Works (EXW) only; excl. VAT**
- **Packaging** based on IMD-PQS specification requirements

Table 4b. – Price details **(RTMDs only)**

	Indicative median price	Currency (USD or EUR)
Hardware purchase price per unit *(NOT including any communications, service)* *MANDATORY*		
1-year contract price per unit *(INCLUDING hardware, communications, service)* *MANDATORY*		

SECTION 5. CHANGES IN MANUFACTURING PROCESS MANDATORY

INSTRUCTIONS: **Manufacturers and product resellers are required to disclose when product alterations or process changes have occurred according to ISO 9001:2015.**

Manufacturers and product resellers are therefore required to **provide supporting documents for every process or product change** that has taken place since the last IMD-PQS Annual Review (qualification renewal).

Table 5 – Changes in manufacturing process

	Status	Details of alterations
Are there any changes to the **manufacturing process**?	YES ☐ NO ☐	
Are there any changes to **any component** of the product?	YES ☐ NO ☐	

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SECTION 6. COMPLAINTS, MALFUNCTIONS AND FAILURES MANDATORY

INFORMATION:

The principle objective of equipment performance reporting is to inform and enable WHO IMD-PQS to adjust specifications should it be identified that performance issues can be addressed by so doing.

A second objective is to collaborate with manufacturers to address CAPA in a timely manner.

Prompt and responsible handling of complaints and failures with actions and follow-up is a requirement of an ISO certified QMS. Manufacturers AND product resellers should be aware that **failures that are not properly addressed (i.e. according to quality procedures) will be taken into consideration by the IMD-PQS Annual Review Committee** and, in some cases, may lead to the suspension of a product's prequalified status.

INSTRUCTIONS:

Manufacturers AND product resellers are required to complete the table below indicating equipment performance failures reported between the last and current prequalification review. Equipment failures should include, but are not limited to, defects in production, poor performance, product recalls, and other reported complaints including condensation issues.

Please detail each type of complaint (involving 1 or more units) separately.

Manufacturers are required to refer to the WHO IMD-PQS post-market monitoring (PMM) **taxonomy** to describe and detail all reported equipment performance failures of products **in category E003** in Table 4. The category E003 taxonomy is provided in English and in French.

TAXONOMY:
https://apps.who.int/immunization_standards/vaccine_quality/IMDPQS_catalogue/catdocumentation.aspx?id_cat=17.

****All information provided by the manufacturer will be treated in the strictest confidence****

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Table 6. - Complaints, malfunction and failures

Date reported	Reported by (source)	Details of complaint / failure	***Provide*** **the Root Cause Analysis conclusions.** ***Note that for E003 products, the IMD-PQS taxonomy is expected to be used.***[1]	No. of units involved	***Describe*** **the corrective AND preventive action (CAPA) taken**	**Current status: Opened, Under investigation OR Closed**[2]**.**

[1] See IMD-PQS Taxonomy definitions on a separate sheet.

[2] Note that the file cannot be closed unless there has been a root-cause analysis, corrective action and preventative action.

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SECTION 7. PRODUCT SHEET CHANGES

MANDATORY

INFORMATION: Manufacturers AND product resellers are responsible for checking that their products are correctly listed in the IMD-PQS Catalogue[3]. The text box below can be filled out to point out errors and/or request edits to the IMD-PQS product sheets.

INSTRUCTIONS: Report separately any changes required to: "**administrative**" information (Description, Manufactured in, Company, address, contact details) in **Table 5a**, and "**technical**" information (product specifications and attributes) in **Table 5b**.

Product sheet changes information must be TYPED into this box (not hand-written) and the document must be submitted in word.doc format (not .pdf).

ALWAYS include a copy of the relevant Product Data Sheet(s) from the IMD-PQS catalogue in your submission. In case edits will be required, please HAND-ANNOTATE, in red font where possible, the sections where those edits will be needed.

Table 7a. - Changes to Product Data Sheet ADMINISTRATIVE INFORMATION

Table 7b - Changes to Product Data Sheet TECHNICAL INFORMATION

[3] http://apps.who.int/immunization_standards/vaccine_quality/IMDPQS_catalogue/PdfCatalogue.aspx?cat_type=device

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SECTION 7. REMARKS / OTHER INFORMATION MANDATORY

This section can be used to share general remarks on the IMD-PQS Annual Review process, the IMD-PQS website[4], or to provide any of other relevant information you would like to provide for the IMD-PQS Secretariat's consideration.

[4] http://apps.who.int/immunization_standards/vaccine_quality/IMD-PQS_catalogue/