unimed
www.unimed.ch

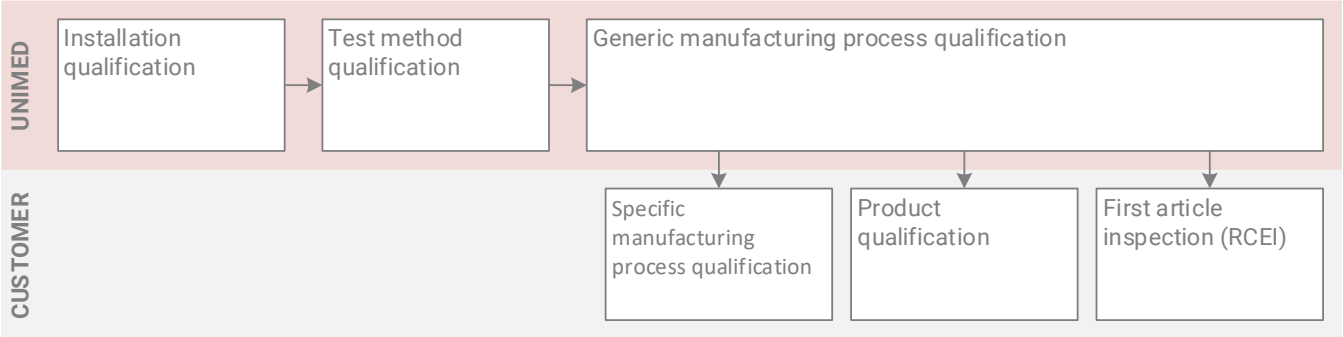
INFORMATION SHEET

Avenue du Tir-Fédéral 56
1024 Ecublens
Switzerland
Tel: +41 21 624 21 51
info@unimed.ch

SUBJECT	QUALIFICATION	SHEET #	QUALIFICATION.FIE

QUALIFICATION SYSTEM

The following scheme represents the organization of the qualification system.



UNIMED QUALIFICATION

This part of the qualification system is conducted by UNIMED independently from products and customers. It is applicable to all elements entering in the qualification applicable scope.

The following table describes each qualification activity conducted by UNIMED and their specificities.

Activity	Description
Installation qualification	All UNIMED control and production equipment are subject to qualification. The qualification level depends on the nature and complexity of the production or control equipment.
Test method qualification	All UNIMED test methods are subject to qualification. The qualification level depends on the nature and complexity of the test method.
Generic manufacturing process qualification	All UNIMED manufacturing processes are considerate as normal process, so verifiable during production. All critical elements of a product are generally 100% verified.

CUSTOMER QUALIFICATION

This part of the qualification system is discussed between customer and UNIMED when establishing and accepting the product specifications. From the discussion, one of the qualification activities can be chosen a supplementary qualification to be conducted. This qualification work is going to be conducted under contract conditions previously defined and agreed by both parties.

The following table describes each qualification activity proposed to customer and their specificities.

Activity	Description
Specific manufacturing process qualification	The specific qualification of a manufacturing process is conducted through a validation based on the customer demand and specifications previously accepted for the product to manufacture.
Product qualification	The qualification of a product performance manufactured by an established process is conducted based on customer demand and specifications previously accepted for the product to manufacture.
First article inspection (RCEI)	A tighten and specific inspection of customer specifications is conducted on samples coming from the first lot manufactured thought a fFirst article inspection report (RCEI).

CUSTOMER INSTALLATION AND PROCESS

An installation provided by a customer to realize a production or a test step is under its responsibility. The customer must ensure that its qualified status (installation, manufacturing process, test method) and conforms with the intended use of the installation in production realization.

This qualification work can be conducted by UNIMED under contract conditions previously defined and agreed by both parties.