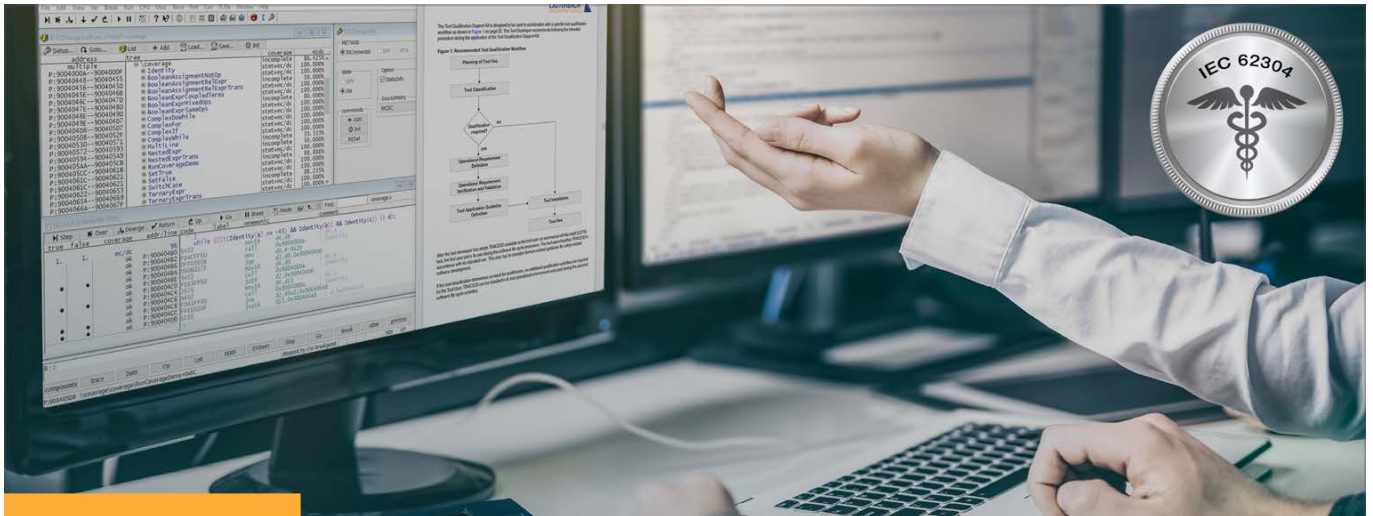# FEATURE OVERVIEW
Using TRACE32 for IEC 62304

TRACE32 for IEC 62304 at a Glance

- TRACE32 Tool Qualification Support-Kit streamlines TRACE32 tool qualification effort and costs.

- TRACE32 TQSK is fully featured, field proven and ready to cover new use cases and requirements.

- TRACE32 TQSK Customer Interface provides full support and service around tool qualification.

- All test suites run in the target environment and are fully multicore aware.

- Test Suite Coverage includes statement, decision, condition, function and call coverage, as well as MC/DC.

- TRACE32 Instruction Simulator, TRACE32 Debug and Trace Tools, USB Debug and Trace provide comprehensive tool support throughout all project phases.

Website-Links

TRACE32 Trusted Tools for Functional Safety	www.lauterbach.com/trusted_tools.html
TQSK Customer Portal	www.lauterbach.com/register_tqsk.html
TRACE32 Code Coverage	www.lauterbach.com/coverage.html
TRACE32 Instruction Set Simulator	www.lauterbach.com/sim.html

The TRACE32 Tool Qualification Support-Kit (TQSK) provides everything needed to qualify TRACE32 tools for use in safety-related medical device software projects.

Tool Qualification Process

The toolchain in safety-critical projects usually consists of a large number of software tools. Knowledge about the use of the individual tools and their embedding in the project environment is essential for the qualification approach in accordance with IEC 62304. The tool user has the final responsibility for establishing confidence in all tools that support required tasks or activities. But the tool provider can prepare everything in such a way that the final qualification can be done with little effort.

The tool provider can, in the case of commercially available (COTS) tools, prepare the documentation required for the qualification process, develop appropriate test suites for each use case of the tool, perform a pre-qualification, and make the resulting data available to the tool users in the form of a Tool Qualification Support-Kit (TQSK). Figure 1 illustrates the 2-stage qualification process Lauterbach has decided to use.

Tool Qualification Support-Kit

The current version of TRACE32 TQSK (v3.2 from March 2022) contains all documents necessary to accomplish and complete the tool qualification for any software safety class and, most importantly, the "Developer Safety Manual". The included test suites cover the tool use cases Coverage and Debug. Both test suites can be used by TRACE32 customers free of charge.

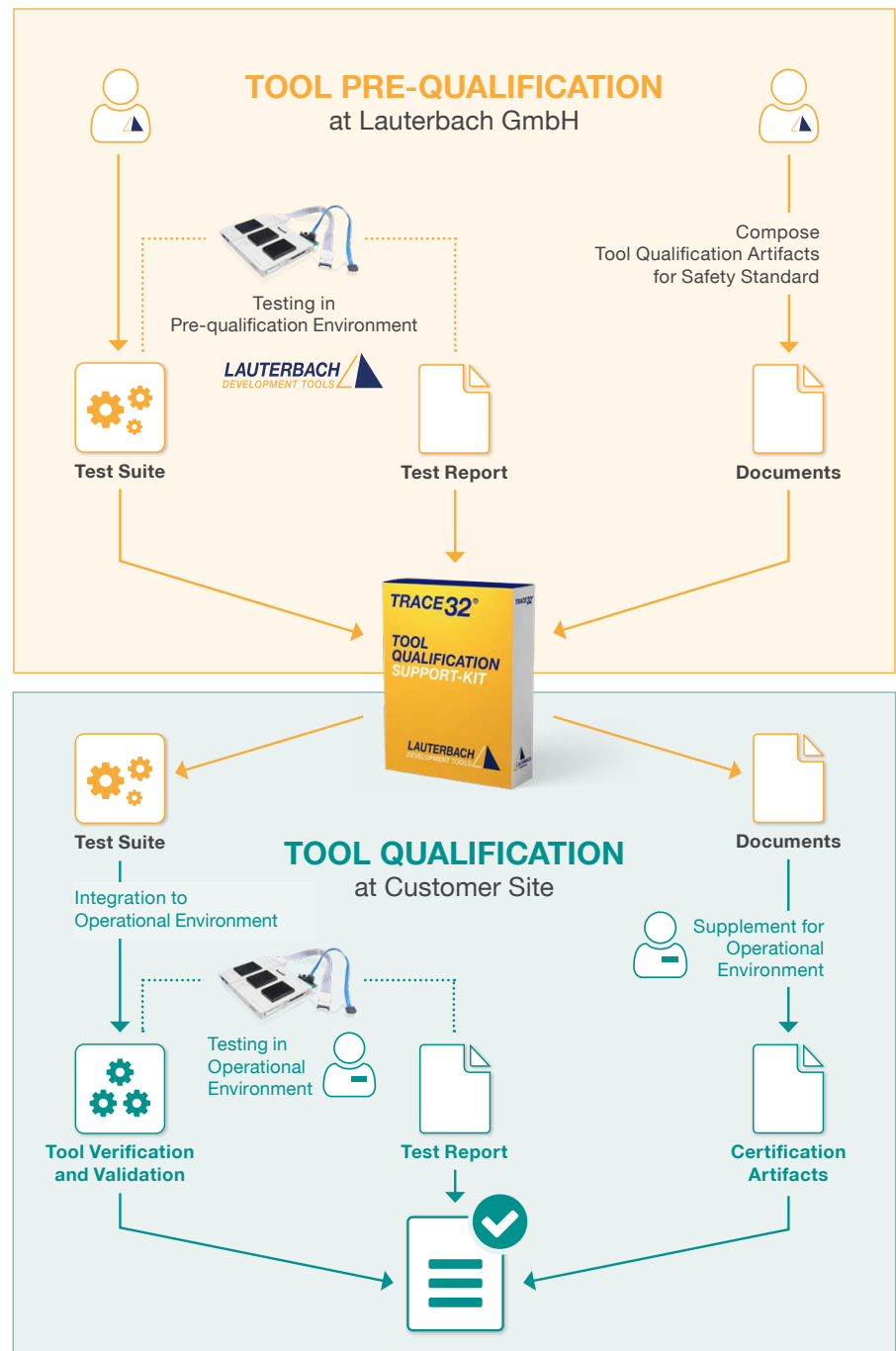The paid test suites Simulator Arm and Simulator TriCore allow the TRACE32

Figure 1: The 2-stage qualification process

TRACE32 Tool Qualification Support-Kit

DSM
Developer Safety Manual

DTOR
Developer Tool Operational Requirements

DTQP
Developer Tool Qualification Plan

TOVVCP
Developer Tool Verification and Validation Cases and Procedures

TOVVR
Developer Tool Operational Verification and Validation Results

General Documentation

TSC
Test Suite Coverage (free)

TSD
Test Suite Debug (free)

TSSTC
Test Suite Simulator TriCore (paid)

TSSA
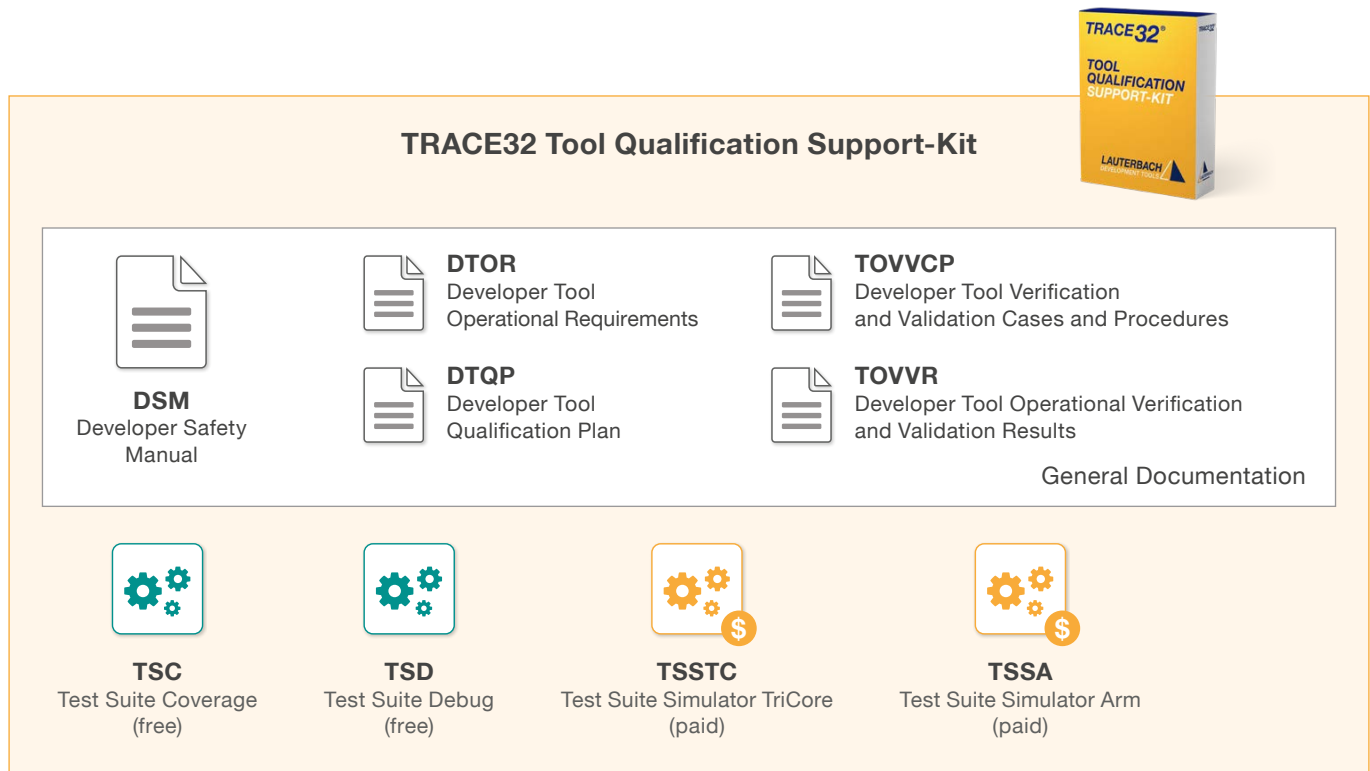Test Suite Simulator Arm (paid)

Figure 2: TQSK structure as of March 2022

Instruction Set Simulator for both core architectures to be qualified as a tool for use in a safety-related project.

All test suites run in the target environment and are fully multicore aware. Like all Lauterbach solutions, TRACE32 TQSK is fully featured, field proven and ready to cover new use cases and requirements. Figure 2 gives an overview of its current structure.

Lauterbach manages its own *TQSK Customer Interface* to provide its customers with a complete service for tool qualification. This includes for registered customers:

- Download of personalized versions of TQSK

- Access to all notable TQSK-related changes to the TRACE32 software and all known TQSK-related issues and their status

The individual test suites and the use cases they cover are described in the following.

Test Suite Coverage

Structural coverage is among the tool use cases that need to be qualified in all cases. TRACE32 offers trace-based code coverage and supports the following coverage metrics for software system testing:

- Statement coverage
- Decision coverage
- Condition coverage
- Function coverage
- Call coverage
- MC/DC

Customers using TRACE32 Test Suite Coverage for their qualification benefit not only from the many core architectures that Lauterbach supports, but also from a comprehensive tool support (see figure 3 on the next page).

- TRACE32 Instruction Set Simulator: Software system testing can be started even before any development hardware is available.

- TRACE32 JTAG debugger and trace: As soon as the development hardware is available, the classic TRACE32 hardware-assisted debug and trace tools can be used for all test phases.

- TRACE32 USB: Even for integration testing, where the embedded hardware might be already deeply embedded in a medical equipment, code coverage analysis can still be performed via the TRACE32 debugger as long as the chip under test allows debugging and tracing via the USB stack.
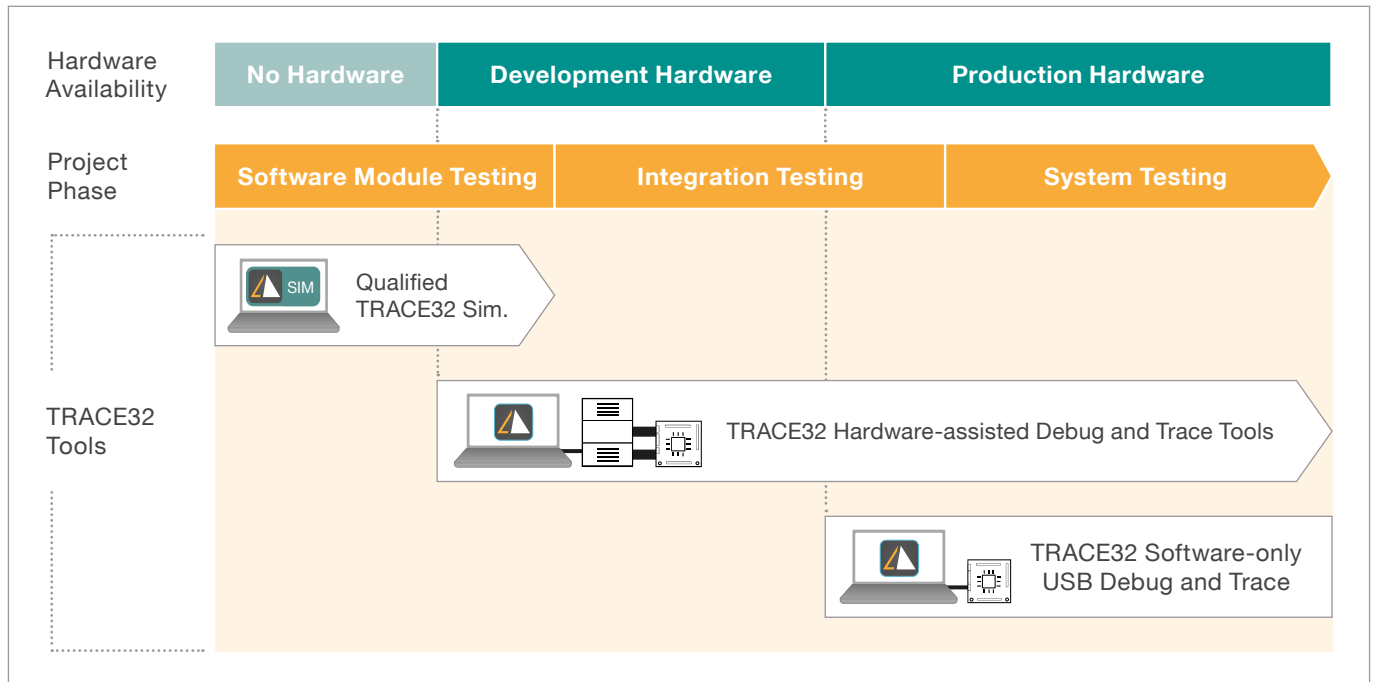
FEATURE OVERVIEW

Figure 3: TRACE32 tool use in code coverage qualification

Test Suite Simulator

Upon customer request, Lauterbach also provides test suites for its Arm and TriCore Instruction Set Simulators. A qualified instruction set simulator is an accepted test environment in the software module testing phase of the project (see also figure 3) and offers the following advantages:

- Product software qualification can start before product hardware is available.

- The qualification of the product software can be well organized even in a distributed team, because everything necessary is purely software-based.

- If bottlenecks occur during this phase due to a lack of development hardware or debug/trace tools, additional test benches can be easily equipped with simulators.

Test Suite Debug

The Test Suite Debug includes all basic debugging functionality such as target configuration, programming onchip and NOR flashes, loading programs, setting breakpoints and reading/writing of memory and variables.

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