The European legislation stipulates that personal protective equipment (PPE) must comply with the regulations in the European Regulation (EU) 2016/425 (PPE Regulation) prior to placing it on the market. This is ensured, among other things, by a mandatory EU-Type Examination (see Annex V of the PPE Regulation (Module B)), combined with ‘CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS’ (see Annex VII (Module C2) or the “Checking of PPE manufactured” (see Annex VIII of the PPE Regulation (Module D))

In practice, the basis for an EU-Type Examination is testing and compliance with a harmonized standard (e.g. EN 137:2006 for a self-contained open-circuit compressed air breathing apparatus). The EU-Type Examination is conducted with the complete samples (“system”) of the PPE handed in by the respective manufacturer, as well as their associated technical documentation according to Annex III of the PPE Regulation. This PPE “system” for a self-contained compressed air breathing apparatus must include the facePieces, lung demand valves, harness/carrying systems, pneumatic assemblies, valved-cylinders and any accessories (otherwise it is not a PPE!)

When the examination is completed with positive results, a corresponding EU-Type Examination certificate is issued. This EU-Type Examination certificate describes the complete product handed in by the manufacturer for examination. With the annual “Checking of PPE manufactured”, the conformity of the product manufactured with the samples handed in for the EU-Type Examination is checked and confirmed correspondingly.

In case of a subsequent change of the PPE described in the EU-Type Examination certificate, without a re-examination (e.g. a third party using the breathing apparatus but with a cylinder/valve not designed/tested/assembled/generated under the control of the original breathing apparatus manufacturer), the EU-type examination certificate loses its validity and therefore must no longer be used according to the European directive 89/391/EEC "Introduction of measures to encourage improvements in the safety and health of workers at work" as well as the European directive 89/656/EEC "Minimum health and safety requirements for the use by workers of personal protective equipment at the workplace".