SCOOP

THE LATEST TRENDS, SERVICES & PROMOTIONS

EXEMPTIONS IN ANNEX IV OF ROHS DIRECTIVE UPDATED

RoHS Directive (**R**estriction **o**f the use of certain **H**azardous **S**ubstances **(RoHS)**), which refers to directive 2011/65/EU, was published by the European Union (EU) aiming to reduce the amount of hazardous substances used in electrical and electronic products. Since then, several exemptions were granted to specific applications which are scientifically or technically infeasible to be replaced.

The exemptions of ***RoHS Directive (2011/65/EU)*** are listed in Annex III and Annex IV. The exemptions in Annex III are suitable for all EEE. Meanwhile, the exemptions in Annex IV are only suitable for medical devices and monitoring and control instruments.

On November 15, 2021, the European Commission published Directives (EU) 2021/1978, (EU) 2021/1979 and (EU) 2021/1980, adding exemptions 45, 46 and 47 to Annex IV of RoHS Directive.

ENTRY #	EXEMPTION	EXPIRY DATE
45	Bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids.	21 July 2028
46	Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils.	1 January 2024
47	Bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer	21 July 2028

Notes:

1. The exemption of which an application for renewal was submitted in due time is under evaluation. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission. If the application for renewal of an exemption is rejected or that an exemption is revoked, the exemption shall expire at the earliest 12 months after the date of the decision. If the application is accepted, the period of validity shall be issued.
2. The exemption of which no application for renewal was submitted in due time, only applies to in vitro diagnostic medical devices in category 8, industrial monitoring and control instruments in category 9 and category 11, other subcategories have expired. In vitro diagnostic medical devices are valid until July 21, 2023, industrial monitoring and control instruments and category 11 equipment are valid until July 21, 2024.

*With a proven track record in product safety certification, **SGS'** global network of RoHS accredited labs and specialists are the ideal partner to verify your compliance to RoHS.*

Please contact our Customer Service Team for more information!

FOR ENQUIRIES

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