“We finished our RoHS effort”, this must be a misunderstanding.

Medical Devices came into scope for RoHS on 22 July 2014, while many other products have been in scope for years already. The regulations require that you have the evidence complete and in hand before importing to the EU after certain dates. So yes, many people would be correct, that they updated/converted/revised their products for RoHS and added a Declaration of Conformance for RoHS to their CE Mark technical file.

It is very important to note that RoHS compliance is not a onetime activity. The regulation states that a Manufacturer is obligated to put procedures in place to ensure Electrical & Electronic Equipment (EEE) manufactured by means of series production will remain compliant. The compliant status of the product must not be corrupted by changes that you make to the product after making the Declaration of Conformance. Most manufacturers change component parts of their products due to end-of-life, cost, location, supplier, obsolescence, and other reasons. These changes must not be allowed to corrupt the product conformance. Your Engineering Change Order (ECO) and related processes need to have review steps, either integrated or added, that require the new or revised parts to be declared and found to comply with RoHS. This must be confirmed and documented before production release of the ECO.

Many manufacturers are changing 20-30% of the parts of their product every year. Let’s use a 500 part medical device as an example. About 6 months have elapsed since July 2014. Potentially ECOs would have been processed for 50 –

75 component part changes. If any of these parts is not documented or not RoHS compliant, then your company has violated the RoHS regulation, and must take corrective measures to fix the sold products and inform surveillance authorities.

Additionally, there are exemptions being retired. One exemption did expire in 2014. If this exemption had been previously invoked for a part within your product, then your product may no longer be compliant.

There are also 4 new substances added to RoHS that go into effect in 2019.

So RoHS compliance of your products must be continuously monitored and maintained after you have finished the initial review and reporting effort. In summary, it is recommended that your company has the following key actions in place:

1. Product Change Control (ECO and related) processes updated to include declaration collection and assessment for RoHS
2. Periodic or specific event triggered reviews of Product RoHS status (especially for Exemption expirations or Regulation updates)
3. All the above have specific owners with defined roles & responsibilities
4. Periodic internal audit of RoHS related processes for compliance.

These controls will help maintain your products RoHS compliant forevermore.

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