1. Obtain a Request for Certification Form, RA001 or Form Folder in Outlook.
2. Fill in Model Number(s), Countries to be covered, and contact information, with as much other available information as possible.
3. If only requesting CE Marking, Form EN039 can be used in place of or in addition to RA001 or Outlook Form.
4. Forward the Form(s) and any supporting documents to Regulatory Affairs.
5. Regulatory Affiars will conduct a preliminary review, and will contact the Requestor if additional information or clarification is required.
6. Once the preliminary review is completed, Regulatory Affairs assigns a request number in the following format: X-YY-xxx (with X being alpha characters A to L, indicating the Month – A being January, L being December. YY is the two digit numeric Year. And xxx being a 3 digit sequence number followed by a model indicator (in parenthesis).
7. All correspondence or documentation associated with the request should refer to this number whenever possible.
8. If the requested Certification already exists, Regulatory Affairs will send a copy of the Certification to the Requestor.
9. Regulatory Affairs adds the Request to the Product Certification Review spreadshhet for tracking
10. Completed Request Forms are reviewed by the Enginnering Certification committee at regularly scheduled meetings (usually weekly). Progress on the certification process are discussed during the meeting and published in a spreadsheet format, available for viewing at [R:\Quality\Records - Certification Requests (RA001 forms)\2018\Certification Request Log 2018.xlsx](file:///\\NYDFS01\Shared\Quality\Records%20-%20Certification%20Requests%20(RA001%20forms)\2015\Certification%20Request%20Log%202015.xlsx)
11. The committee will determine which applications are needed, what testing is required, and/or whether a more expedited method is available for certification. Also:
    1. If the request is for New CE marking or includes CE Marking, Engineering will conduct a preliminary Review of EMC/Safety requirements and determine if new testing is required or if CE for EMC/Safety is covered by “Similarity” to a tested sensor. This decision, and the rationale for the decision, will be recorded on Form EN039 by a Qualified Engineer.
    2. All CE Marked product must also be assessed for all other Applicable EC Marking Directives, including the RoHS Directive. For “self-certification” Directives, these assessments will also be recorded on EN039. For non-self-certification Directives, follow the normal Certification Request path.
    3. If all applicable “Essential Requirements” of the Directives have been fulfilled the CE Mark may be included on the Product Specification.
    4. If an EN039 Form is not used for recording a CE Decision, then the justification and assessment information shall be included in the Design History File documentation.
12. Based on the Committee recommendations, Regulatory Affairs will obtain quotes from the appropriate Certification agencies.
13. Regulatory Affairs and Engineering will then calculate an Expense Estimate for the certification.
14. The RA001 Form with the Expense Calculation in Box 4, or an e-mail attached to the OutLook Form with an Accept/Reject decision box is then forwarded to the responsible Sales/Product Manager for review. The certification request approval or rejection is recorded in Box 5 on the form, or the e-mail response to Accept/Reject is returned to Regulatory Affairs for futher processing.
15. If a request is not approved, the Requestor (if different) will be notified and a copy of th rejected request is forwarded to them for their records. There is no appeals process established. A new Request should be initated for the Certification if a new opportunity is identified after the initial application is rejected.
16. Approved Quotes are processed by Regulatory Affairs/Engineering including preparation of any required samples, purchase requistions, test requests, and other necessary documentation.
17. Results of any required testing, drawing, specification, or other required documentation is forwarded to the Certification agencies by Regulatory Affairs/Engineering. (Note: May require multiple iterations)
18. Once the Certifications are issued, Regulatory Affairs (with support from Engineering) will execute the documentation updates required for the type of certification received, including (but not limited to) the following:
    1. Submit ECO to have required drawings created or modified. Documents to be included are shown below. DIN\_\_\_\_\_\_\_\_\_\_\_\_\_
       1. - Technical Files
       2. - Descriptive Notices
       3. - Etching control drawings
       4. - Any other Labeling, including Manuals and IFUs
    2. Release approved drawings, close ECO from step 1.
    3. Review etching samples. Correct if necessary. Once ok, sign off TA012 and hold until final ECO is released.
    4. If the Certifications are new, obtain “CT” (Certification) number from Regulatory Affairs and add these CT numbers to the BOM along with the associated Declaration of Conformity (“PS”) number. It the Certifications are updates, check to make sure that the “CT” numbers associated with the certification are correct. No further action from Engineering/Drafting is required.
    5. Once final ECO is released, return TA012 etching drawing and etch to new approvals.
19. Update IDFinal,docx in the R:/TCS/CT Folder with new Certificate numbers and “PS” Reference (as applicable).
20. After all the Certification Request tasks are completed, an electronic copy of the request is stored in the database under R:/Quality/Records - Certification Requests/Year (i.e. 2018) by Request Number.