

One Device. Three Pathways.

How ETL, CB Scheme and FDA ASCA support different compliance objectives.



ETL
North America Certification



CB Scheme
International Certification
Pathway



FDA ASCA
U.S. Premarket
Submissions

Purpose

Accredited third-party
product certification

Test data based on
harmonized IEC standards

FDA-recognized
conformity assessment
for pre-market approvals

Primary Outcome

ETL Certification and
Authorization to Mark

CB Test Certificate and
Report

ASCA Summary Test
Report

Best Fit

Medical Electrical
Equipment entering the
North American market

Medical Electrical
Equipment requiring
global regulatory
approvals

Medical device
manufacturers wanting to
simplify their FDA
pre-market submissions

Complementary Paths, Not Interchangeable.

Multiple strategies that enable faster, more efficient market access to global markets.

